DEPARTMENT OF AGRICULTURE (USDA)

Statement of Regulatory Priorities

The Department of Agriculture continues to implement an ongoing program to eliminate unnecessary regulations and improve those remaining by making them easier to understand and more user friendly. Positive changes resulting from this regulatory reform initiative will reach into every corner of the country and, both directly and indirectly, touch the lives of most Americans. Those programs that offer support to specific rural and urban segments of the economy are being simplified so that persons who qualify for assistance, or some other form of participation, will find less burdensome rules. Yet high standards are in place to ensure efficient and effective program management that makes the best use of taxpayer dollars. Farmers, ranchers, and other USDA customers will find significant changes in all aspects of regulations that govern their interaction with the Department and its programs. Farm credit, a mainstay of the Nation's rural economy, is being significantly streamlined by the merger of cumbersome loan-making regulations with forms and certifications simplified to facilitate the application process. The Department is undertaking a number of actions in the regulation of commodities that will increase efficiency, improve customer service, reduce intervention in markets, and allow States to assume greater responsibility in controlling the spread of plant and animal pests or disease. The Department is also improving the regulations that serve rural communities. Several changes are being made in rural housing programs that will facilitate access and simplify the application process. Nutrition programs are also being strengthened, their efficiency improved, and their integrity enhanced through regulatory actions. In the area of food safety, the Department has undertaken significant revisions to all policies and steps to improve relationships with industry and the public. There are also several important initiatives under development in the natural resources and conservation area.

Reducing Paperwork Burden on Farmers

The Department has made substantial progress under the guidance of the Chief Information Officer in implementing the goal of the Paperwork Reduction Act of 1995 to reduce the burden of information collection on the public. USDA continues to work toward full compliance with the law and to continue reducing burden by an additional 5 percent during fiscal year 2001. Further reductions will result from program changes, improved efficiency in the collection and management of information, and adjustments in the collection burden.

The Government Paperwork Elimination Act (GPEA) is leading all agencies in the Department to evaluate how they conduct business and migrate toward electronically oriented methods. The Farm Service Agency, Natural Resources Conservation Service, Rural Development, and Risk Management Agency are also working to implement the recently passed Freedom to E-File Act. Freedom to E-File directs the agencies, to the maximum extent practicable within 180 days, to modify forms into user-friendly formats with user instructions and permits those forms to be downloaded and submitted via facsimile, mail, or similar means. Within 2 years producers should have the capability to electronically file forms and all other documentation if they so desire. Underlying these efforts will be analyses to identify and eliminate redundant data collections and streamline collection instructions. The end result of implementing both of these pieces of legislation will be to better service to our customers so that they can choose when and where to conduct business with USDA.

The Role of Regulations

The programs of the Department are diverse and far reaching, as are the regulations that attend their delivery. Regulations codify how the Department will conduct its business, including the specifics of access to, and eligibility for, USDA programs. Regulations also specify the behavior of State and local governments, private industry, businesses, and individuals that is necessary to comply with their provisions. The diversity in purpose and outreach of our programs contributes significantly to the USDA being at or near the top of the list of departments that produce the largest number of regulations annually. These regulations range from nutrition standards for the school lunch program, to natural resource and environmental measures governing national forest usage and soil conservation, to regulations protecting American agribusiness (the largest dollar value contributor to exports) from the ravages of domestic or foreign plant or animal pestilence, and they extend from farm to supermarket to ensure the safety, quality, and availability of the Nation's food supply. Many regulations function in a dynamic environment, which requires their periodic modification. The factors determining various entitlement, eligibility, and administrative criteria often change from year to year. Therefore, many significant regulations must be revised annually to reflect changes in economic and market benchmarks. Almost all legislation that affects departmental programs has accompanying regulatory needs, often with a significant impact. The Farm Bill of 1996, Public Law 104-127, has considerable regulatory consequences. This key legislation affects most agencies of USDA and will result in the addition of new programs, the deletion of others, and modification to still others. In addition, the most recently enacted Agricultural Risk Protection Act of 2000, Public Law 106-224, provides further assurances that agricultural programs will continue to achieve long-term improvements, particularly in reforms to the crop insurance programs. This legislation also provides for improvements in market loss and conservation assistance, crop and livestock disease pest protection, marketing program enhancements, child nutrition program measures, pollution control, and research and development for biomass.

Administration Guidance—USDA Response

In developing and implementing regulations, the Department has been guided by the regulatory principles and philosophy set forth by the President in Executive Order 12866 ''Regulatory Planning and Review.'' As prescribed in the Order, the USDA is committed to ''promulgate only those regulations that are required by law, are necessary to interpret the law, or are made necessary by compelling public need.'' When considering a rulemaking action, the Department will assess the costs and benefits of available regulatory alternatives, including the alternative of not regulating. Our analysis will consider the costs and benefits of both quantifiable and qualitative measures and opt for approaches that maximize net benefits.

Major Regulatory Priorities

Seven agencies are represented in this regulatory plan. They include the Farm Service Agency, the Food and Nutrition Service, the Forest Service, the Food Safety and Inspection Service, the Animal and Plant Health Inspection Service, the Agricultural Marketing Service, and the Grain Inspection, Packers and Stockyards Administration.

This document represents summary information on prospective significant regulations as called for in Executive Order 12866. A brief comment on each of the six agencies appears below, which summarizes the Agency mission and its key regulatory priorities. The Agency summaries are followed by the regulatory plan entries.

Farm Service Agency

Mission: The Farm Service Agency (FSA) administers contract commodity, conservation, farm loan, commodity purchase, and emergency loan and disaster programs, as prescribed by various statutes, in order to support farming certainty and flexibility while ensuring compliance with farm conservation and wetland protection requirements and to assist owners and operators of farms and ranches to conserve and enhance soil, water, and related natural resources.

Priorities: FSA's priority for 2001 will be to continue to implement these programs with emphasis on enhanced service to our customers. The most significant FSA regulations are those that operate the contract commodity programs and farm loans. The farm programs were significantly changed by the 1996 Farm Bill. The Farm Bill instituted the contract commodity programs, which utilize production flexibility contracts and marketing assistance loans in place of the deficiency payments and production adjustment of past programs. The contracts removed the link between income support payments and farm prices by providing for seven annual fixed but declining payments. FSA's farm loan programs make and guarantee loans to family farmers and ranchers to purchase farmland and finance agricultural production. While the contract commodity and farm loan programs have significant economic impact, they are driven by specific statutory requirements. Therefore, they are noted here to acknowledge their significance in the overall USDA regulatory plan but are not further listed in the body of the plan, which appears below.

In addition to its normal program operations, FSA is committed to the Paperwork Reduction Act of 1995's goal of reducing the information collection burden on the public. FSA is streamlining its farm loan-making and servicing regulations and reducing the information collection burden associated with the programs. FSA plans to reduce the number of CFR parts containing its farm loan program regulations by approximately 70 percent. In addition, FSA hopes to achieve a significant reduction in the total number of CFR pages by removing administrative provisions and internal policy and eliminating duplicative material. Furthermore, FSA intends to improve the clarity of the farm loan program regulations by following the guidelines established in the President's Plain Language in Government Writing Initiative.

As part of this project, all farm loan program regulations and internal Agency directives will be completely rewritten. All application processes and information collections will be reviewed, and unnecessary or redundant requirements will be eliminated. All forms associated with the program were reviewed and assigned to one of the following categories:

- Prepared by the public
- Prepared by the Agency, reviewed by the public, or
- Internal Agency use only.

FLP will concentrate on streamlining forms assigned to the first category to reduce public burden. In addition, a data base was developed listing each field contained on the forms. This information will be used to identify duplicate collections and ensure consistency in terminology.

FSA plans to publish regulations for direct loan program and administrative regulations as a proposed rule in December 2000 and as a final rule in September 2001. While rewriting of the regulations has begun, it will be a lengthy process because approximately 37 CFR parts are being consolidated into 3 parts and more than 750 CFR pages must be rewritten. Revised regulations for special loan programs (including Indian land acquisition, boll weevil eradication, drainage and irrigation, and grazing association loans) are planned for publication as a proposed rule in August 2001 and as a final rule in April 2002. These programs will be completed last because there are only about 850 borrowers with outstanding special loans in comparison to almost 110,000 borrowers with outstanding direct loans.

Food and Nutrition Service

Mission: FNS increases food security and reduces hunger in partnership with cooperating organizations by providing children and low-income people access to food, a healthful diet, and nutrition education in a manner that supports American agriculture and inspires public confidence.

Priorities: In addition to responding to provisions of legislation authorizing and modifying Federal nutrition assistance programs, FNS's 2001 regulatory plan supports broad goals and objectives in the Agency's strategic plan, which was extensively revised in fiscal year 2000. The goals are:

- Improved nutrition of children and low-income people. This goal represents FNS's efforts to improve diet quality as measured by scores on the Healthy Eating Index by providing access to program benefits (Food Stamps, WIC food vouchers, commodities and State administrative funds), nutrition education, and quality meals and other benefits. It includes three major objectives: 1) Improved food security, which reflects nutrition assistance benefits issued to program participants; 2) FNS program participants make healthy food choices, which represents our efforts to improve nutrition knowledge and behavior through nutrition education and breastfeeding promotion; and 3) improved nutritional quality of meals, food packages, commodities, and other program benefits, which represents our efforts to ensure that program benefits meet the appropriate nutrition standards to effectively improve nutrition for program participants.
- Improved Stewardship of Federal Funds. This goal represents FNS's ongoing commitment to maximize the accuracy of benefits issued, maximize the efficiency and effectiveness of program operations, and minimize participant and vendor fraud. It includes two major objectives: 1) Improved benefit accuracy and reduced fraud, which represents the Agency's effort to reduce participant and Agency errors and to control Food Stamp and WIC trafficking and participant, vendor, and administrative Agency fraud; and 2) improved efficiency of program administration, which represents our efforts to streamline program operations and improve program structures as necessary to maximize their effectiveness.

Forest Service

Mission: The mission of the Forest Service is to sustain the health, productivity, and diversity of the Nation's forest and rangelands to meet the needs of present and future generations. This includes protecting and managing the National Forest and Grasslands; providing technical and financial assistance to States,

communities, and private forest landowners; and developing and providing scientific and technical assistance and scientific exchanges in support of forest and range conservation.

Priorities: On October 13, 1999, the President issued a memorandum directing the Forest Service to develop and propose for public comment regulations to provide appropriate long-term protection for most or all of the currently inventoried ''roadless'' areas and to determine whether such protection is warranted for any smaller ''roadless'' areas not yet inventoried. A notice of intent to prepare an Environmental Impact Statement to analyze and disclose various alternatives for meeting the President's directive was published in the **Federal Register** on October 19, 1999. The Agency received approximately 500,000 written responses to the notice of intent.

On May 10, 2000 (65 FR 30276), the Agency published in the **Federal Register** a notice of proposed rulemaking for Special Areas; Roadless Area Conservation. The Agency proposes to prohibit road construction and reconstruction in most inventoried roadless areas of the National Forest System and require evaluation of roadless area characteristics in the context of overall multiple-use objectives during land and resource management plan revisions. The Agency conducted over 440 public meetings and is maintaining a web page with additional information. The final rule, Special Areas, Roadless Areas Conservation, is expected to be published in early winter.

Another Agency priority is to revise its road management rules and policy to better inventory and analyze the need for existing forest roads, and to shift the emphasis from building new roads to better maintaining and managing those already in use. The final rule and final policy, Administration of the Forest Development Transportation System, are expected to be published in the fall.

Finally, the last of three Agency priorities is to revise the land management planning regulations to make sustainability the foundation for national forest system planning and management and establish requirements for implementation, monitoring, evaluation, amendment, and revision of land management plans. A proposed rule was published in the **Federal Register** on October 5, 1999 (Part II, 64 FR 54074-54112). Guided by recommendations of a Committee of Scientists, the proposed rule provides for science-based planning, ecosystem sustainability, use of ecoregional and watershed-level assessments, and strengthened collaboration with individuals or organizations, State, local, tribal governments, and other Federal agencies. The final rule, National Forest System Land and Resource Management Planning, is expected to be published this fall.

Food Safety and Inspection Service

Mission: The Food Safety and Inspection Service (FSIS) is responsible for ensuring the Nation's meat, poultry, and egg products are safe, wholesome, and properly marked, labeled, and packaged.

Priorities: FSIS is continuing to review its regulations to eliminate duplication of and inconsistency with its own and other agencies' regulations. The review effort is directed, in particular, at improving the consistency of the regulations with the July 25, 1996, final rule ''Pathogen Reduction; Hazard Analysis and Critical Control Points (HACCP) Systems.'' HACCP is a science-based process control system for producing safe food products. The final rule requires official meat and poultry establishments to develop and implement HACCP plans incorporating the controls they have determined are necessary and appropriate to produce safe products. HACCP places the responsibility for food safety firmly on meat and poultry establishments but enables them to tailor their control systems to their particular needs and processes and to take advantage of the latest technological innovations.

In addition, FSIS must revise its numerous ''command-and-control'' regulations, which prescribe the exact means establishments must use to ensure the safety of their products, in effect assigning to the Agency the responsibility for the means used by establishments to comply with the regulations. As a general matter, command-and-control regulations are incompatible with HACCP because they deprive plants of the flexibility to innovate and undercut the clear delineation of responsibility for food safety. Therefore, FSIS is conducting a thorough review of its current regulations and, to the maximum extent possible, converting its command-and-control regulations to performance standards.

Following are some of the Agency's recent and planned initiatives to convert command-and-control regulations to performance standards, to streamline and simplify the regulations and to make the meat, poultry products, and egg products inspection regulations more consistent with the pathogen reduction and HACCP systems final rule:

- FSIS has proposed new regulations limiting the amount of processing water that can be retained by raw, single-ingredient, meat or poultry products and requiring labeling to indicate the amount of water retention.
- FSIS has proposed to clarify and supplement the requirements that apply to meat products produced by advanced separation machinery and recovery systems. The proposed rule would replace the compliance program parameters prescribed in 1994 with a requirement that as a prerequisite to labeling or using the product as meat, an establishment must implement and document procedures that ensure the establishments production process is in control.
- FSIS will be proposing generic Escherichia coli process control criteria, based on the sponge method of sampling, for cattle, swine, and geese slaughtering establishments, and for turkey slaughtering establishments based on both the sponge and the whole-bird rinse sampling methods. The Agency also will be proposing updated Salmonella performance standards for all market classes of cattle and swine.
- FSIS also will be proposing a rule to establish food safety performance standards for all processed ready-to-eat and partially heat-treated meat and poultry products.
- In addition, FSIS will be proposing to require federally inspected egg product establishments to develop and implement HACCP systems and sanitation standards operating procedures. The Agency will be proposing pathogen reduction performance standards for pasteurizing egg products. Further, the Agency will be proposing to remove current requirements for approval by FSIS of egg-product plant drawings, specifications, and equipment prior to use and to end the system for premarketing approval of labels for egg products. The Agency also is planning to propose requiring safe-handling labels on shell eggs and egg products.
- Finally, besides the foregoing initiatives, FSIS will be proposing requirements for the nutrition labeling of ground or chopped meat and poultry products and single-ingredient products. This proposed

rule would require nutrition labeling, on the label or at the point-of-purchase, for the major cuts of single-ingredient, raw products and will require nutrition information on the label of ground or chopped products.

Animal and Plant Health Inspection Service

Mission: A major part of the mission of the Animal and Plant Health Inspection Service (APHIS) is to protect U.S. animal and plant resources from destructive pests and diseases. APHIS conducts programs to control and eradicate exotic pests and diseases in the United States. These activities enhance agricultural productivity and competitiveness and contribute to the national economy and the public health.

Priority: APHIS is developing a proposal to strengthen restrictions on the importation of solid wood packing material (e.g., crates, dunnage, wooden spools, pallets, packing blocks) into the United States. Imported solid wood packing material (SWPM) has been linked to introductions of exotic plant pests such as the pine shoot beetle and the Asian longhorned beetle. These and other plant pests that could be carried by imported SWPM pose a serious threat to U.S. agriculture and to natural, cultivated, and urban forests. SWPM accompanies nearly all types of imported commodities, from fruits and vegetables to machinery and electrical equipment.

Agricultural Marketing Service

Mission: The Agricultural Marketing Service (AMS) facilitates the marketing of agricultural products in domestic and international markets, while ensuring fair trading practices, and promoting a competitive and efficient marketplace, to the benefit of producers, traders, and consumers of U.S. food and fiber products.

Priorities: AMS' top regulatory priority is to establish the National Organic Program (NOP). The NOP will establish national standards for the production and handling of organically produced products, including a National List of substances approved and prohibited for use in organic production and handling.

On March 17, 2000, AMS published in the **Federal Register** the procedures for Mandatory Market News Reporting of Livestock and Meat. These proposed regulations establish a program that will provide livestock producers, packers, and other market participants with information on pricing, contracting for purchase, numbers and quality marketed for cattle, swine, lambs, and production of livestock products.

On March 24, 2000, AMS published final regulations updating the Federal Seed Act to incorporate current seed testing and seed certification procedures. These regulations will keep the Federal Seed Act consistent with present technology and prevent conflicts between Federal and State regulations that could inhibit the free movement of seed.

On June 6, 2000, AMS published a proposed rule to develop a voluntary, user-fee-funded program to inspect and certify equipment and utensils used to process livestock and poultry products. This service will provide buyers of equipment inspected and certified by this program with a third-party assurance that the equipment meets minimum requirements for cleanability, suitability of materials used in construction, durability, and inspectability. A 60-day comment period was provided for interested persons to comment on the proposed rule before issuing a final rule.

AMS Program Rulemaking Pages. Most of AMS' rules as published in the **Federal Register** are available on the Internet at: http://www.ams.usda.gov/rulemaking. This site also includes commenting instructions and addresses, links to news releases and background material, and comments received so far on various rules.

Grain Inspection, Packers and Stockyards Administration

Mission: The Grain Inspection, Packers and Stockyards Administration (GIPSA) facilitates the marketing of livestock, poultry, meat, cereals, oilseeds, and related agricultural products and promotes fair and competitive trading practices for the overall benefit of consumers and American agriculture. The mission of this Agency is carried out in two different segments of American agriculture. GIPSA's Federal Grain Inspection Service (FGIS) provides the U.S. grain market with Federal quality standards and a uniform system for applying them. The Packers and Stockyards Programs (P&S) ensures open and competitive markets for livestock, meat, and poultry.

Priorities: GIPSA proposes adding five provisions to regulations under the Packers and Stockyards Act to address certain trade and anti-competitive practices in the livestock and poultry sectors. This series of regulations is intended to increase transparency of market transactions and allow market participants to compete more effectively and fairly. The provisions will: (1) Clarify recordkeeping requirements for packers; (2) mandate disclosure of specific production contract terms in plain language; (3) prohibit restrictions on the disclosure of contract terms; (4) require that livestock owned by different people be purchased or offered for purchase on its own merits; and (5) specify conditions under which packers may offer premiums and discounts in carcass merit transactions.

GIPSA will issue an ANPRM in response to an Administration initiative to strengthen the science-based regulations for biotechnology and to improve consumer access to information on biotechnology. The ANPRM will provide a 60-day comment period for input from consumers, industry, and scientists on how USDA can best facilitate the marketing of grains, oilseeds, fruits, vegetables, and nuts in today's evolving markets.

GIPSA is proposing regulations under the P&S Act to implement the Swine Packer Marketing Contracts subtitle of the Livestock Mandatory Reporting Act of 1999. The proposal is intended to establish a swine marketing contract library and provide information on the contracting practices of swine packers.

GIPSA is proposing a regulation that would make purchasing or selling livestock with the condition that the price not be reported a violation of the P&S Act.

GIPSA's rulemaking activities as published in the **Federal Register** are available on the Internet at: http://www.usda.gov/gipsa/strulreg/fedreg/fedreg.htm.

USDA—Agricultural Marketing Service (AMS)

FINAL RULE STAGE

1. NATIONAL ORGANIC PROGRAM

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

PL 101-624, sec 2101 to 2123; 7 USC 6501 to 6522

CFR Citation:

7 CFR 205

Legal Deadline:

NPRM, Statutory, May 28, 1991.

NPRM, Statutory, May 28, 1992.

Final, Statutory, October 1, 1993.

The Organic Foods Production Act calls for the Secretary to appoint the National Organic Standards Board 180 days after enactment and convene it within 60 days thereafter.

Abstract:

The National Organic Program (NOP) would establish national standards for the organic production and handling of agricultural products. It establishes the 15-member National Organic Standards Board (NOSB) who advises the Secretary of Agriculture (Secretary) on all aspects regarding implementation of the NOP and particularly in developing the national list of approved and prohibited substances. It also would establish an accreditation program for State officials and private persons who want to be accredited to certify farms and handling operations that comply with the program's requirements. The program additionally would include labeling requirements for organic products and products containing organic ingredients and enforcement provisions. It further provides for the approval of State organic programs and the importation into the United States of organic agricultural products from foreign producers that meet or are the equivalent to the national standard.

Statement of Need:

The purpose of these regulations is to implement the Organic Foods Production Act (OFPA). The Act requires the establishment of consistent national standards for products labeled as organic; mandatory independent, third-party certification of such products; U.S. Department of Agriculture (USDA) oversight of the independent certifiers and their inspectors; and assurance that imported organic food products are produced and processed under practices equivalent to USDA standards. Establishment of the National Organic Program is necessary to eliminate the confusion that exists among consumers because of the variety of standards under which organic foods are currently produced and the irregular and sometimes unsubstantiated labeling claims.

Summary of Legal Basis:

This regulatory action is authorized by title XXI of the Food, Agriculture, Conservation, and Trade Act of 1990 (Public Law 101-624).

Alternatives:

The Board developed recommendations through an open discussion process with the interested parties. The Board formed six subcommittees to draft recommendations for the following subject areas: Crop standards; livestock standards; processing, packaging, and labeling standards; materials; accreditation of certifying agents; and international (import) requirements. The Board has held 20 meetings during which they have accepted public comments. In addition, the Agency held four public hearings on livestock to develop additional input to the development of livestock standards. In reviewing the Organic Foods Production Act, the Board identified about 25 specific topics requiring recommendation development such as an organic plan, pesticide drift, livestock health, and materials review. Draft documents were prepared in the specific subject areas and circulated for comment from the organic industry. These documents were then further revised with full board-member input and submitted a final time for public comment. Upon receipt of comments, revisions were made, and the document was approved as a recommendation to the Secretary. Approximately 25 of these recommendations were approved at a Board meeting in June 1994 and forwarded to the Secretary (after minor editing in the approval process) in August 1994. In all of the documents, the Board committees considered alternatives and altered positions based on reasoned public comments received. The Board continues to provide recommendations for modification or additions to program recommendations as the program is implemented and operating. The allowed synthetic substances and prohibited natural substances on the national list are subject to review by the Board and the Secretary every 5 years in order for the national list to be valid according to section 2118(e) of the OFPA. The Secretary uses the recommendations as the basis for developing proposed rules for implementing the program. The Secretary may not accept recommendations that are deemed to be inconsistent with Department policy or lack a defensible position. In December 1997, the NOP published a proposed regulation that drew more than 275,000 mostly negative comments from the public. This intense public concern prompted the Secretary to call for the rule to be rewritten. The process included a review of comments, further discussion with the NOSP regarding their recommendations, and publishing for comment three options papers—two dealing with organic livestock practices and one addressing authority of certifying agents. NOP published a second proposed rule March 12, 2000, that received 40,774 comments, most of which are favorable. NOP anticipates publishing a final rule by the end of calendar year 2000.

Anticipated Cost and Benefits:

Implementation of the National Organic Program will benefit certifying agents, producers, handlers, and consumers. Key benefits include improved protection of buyers from misleading claims and more information on organic food, reduced administrative costs, and improved access to international organic markets. The proposed rule would impose direct costs on applicants for accreditation. Certifying agents will be charged fees and related charges when applying for and for annual reviews of accreditation. Estimated direct costs for accreditation are $1,530 to $2,050 during the first 18 months following publication of the final rule. Following the initial 18 months when hourly charges for accreditation service will be charged, the cost for initial accreditation will be $3,070 to $4,850. The cost for the annual review of accreditation is estimated at $190 to $760 depending on the complexity of the certifying agent's business. Certifying agents are expected to pass the costs of accreditation and other costs onto their producer and handler clients. USDA will not impose any direct fees on producers and handlers. However, all industry participants—certifying agents, producers, and handlers—will have costs of compliance, including paperwork and recordkeeping costs. USDA National Organic Program, States operating State programs, and certifying agents will all bear enforcement costs. The amount of enforcement costs is unknown.

Risks:

The program does not address food safety issues. Any reduction in risks to public health, safety, or the environment are indirect benefits of the management practices and substances used by organic producers. Organic producers seek to reduce or eliminate practices and materials that may harm soil life, deplete nonrenewable resources, pose a hazard to water and air quality, or threaten farmworkers health. The Act requires the establishment of a ''national list'' of approved synthetic and prohibited natural materials as an integral part of

the program. Synthetic materials approved for the national list must have been determined by the USDA, FDA, and EPA to be not harmful to human health or the environment.

Timetable:

Action	Date	FR Cite
Organic Livestock Hearings	12/30/93	58 FR 69315
Notice-Procedure To Submit Names of Substances for National List	03/27/95	60 FR 15744
NPRM	12/16/97	62 FR 65850
NPRM Comment Period End	04/30/98	
Issue Papers Published	10/28/98	63 FR 57624
Issue Papers Comment Period Ends	12/14/98	
Second NPRM	03/13/00	65 FR 13512
Second NPRM Comment Period End	06/12/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State, Tribal

Agency Contact:

Keith Jones
Program Manager
Department of Agriculture
Agricultural Marketing Service
Rm. 2945 So.
National Organic Program
Transportation & Marketing Program
P.O. Box 96456
Washington, DC 20090-0645
Phone: 202 720-3252
Fax: 202 690-3924
Email: keith.jones@usda.gov

RIN: 0581–AA40

USDA—Animal and Plant Health Inspection Service (APHIS)

PROPOSED RULE STAGE

2. IMPORTATION OF SOLID WOOD PACKING MATERIAL

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

Title IV of Public Law 106-224; 7 USC 166 and 450

CFR Citation:

7 CFR 319

Legal Deadline:

None

Abstract:

APHIS is undertaking rulemaking to strengthen restrictions on the importation of solid wood packing material (e.g., crates, dunnage, wooden spools, pallets, packing blocks) into the United States. Imported solid wood packing material (SWPM) has been linked to introductions of exotic plant pests, such as the pine shoot beetle and the Asian longhorned beetle. These and other plant pests that could be carried by imported SWPM pose a serious threat to U.S. agriculture and to natural, cultivated, and urban forests. SWPM accompanies nearly all types of imported commodities, from fruits and vegetables to machinery and electrical equipment.

Statement of Need:

Unmanufactured wood articles imported into the United States could pose a serious threat of introducing plant pests detrimental to agriculture and to natural, cultivated, and urban forests. Regulations in 7 CFR 319.40-1 through 319.40-11 are intended to mitigate this plant pest risk. Introductions into the United States of exotic plant pests such as the pine shoot beetle and the Asian longhorned beetle have been linked to the importation of solid wood packing material (an unmanufactured wood article). Solid wood packing material accompanies nearly all types of imported commodities, from fruits and vegetables to machinery and electrical equipment. For this reason, we are undertaking rulemaking to strengthen the regulations that restrict the importation of solid wood packing material in order to reduce the risk that plant pests will be introduced into the United States.

Summary of Legal Basis:

The Animal and Plant Health Inspection Service (APHIS) is authorized to take action under the Plant Protection Act (Pub. L. 106-224).

Alternatives:

APHIS presented three alternatives in an advance notice of proposed rulemaking. The alternatives were to apply restrictions on the importation of solid wood packing material based on risk assessment of regions, apply restrictions on a general basis regardless of origin, and prohibit importation of any solid wood packing material. We accepted comments on other alternatives to consider. These and other alternatives will be considered in analyses prepared in connection with further rulemaking.

Anticipated Cost and Benefits:

The costs of proposed regulatory changes will be dependent on the option that is chosen. We anticipate that costs will be alleviated by utilization of alternative materials, such as nonwood packing material. The benefits of increased restrictions will be the reduction in the risk of potentially destructive plant pests being introduced into the United States and the resulting avoidance of economic losses to forest and agricultural resources. For the Asian longhorned beetle alone (a pest detected on solid wood packing material imported from China), we estimate that, if left unchecked, this pest has the potential to cause economic losses of $41 billion, affecting the forest products, commercial fruit, maple syrup, nursery, and tourist industries in the United States.

Risks:

APHIS will conduct a comprehensive pest risk assessment prior to making any regulatory changes.

Timetable:

Action	Date	FR Cite
ANPRM	01/20/99	64 FR 3049
ANPRM Comment Period End	03/22/99	
Notice	07/07/99	64 FR 36608
Comment Period End	09/07/99	
NPRM	09/00/01	
NPRM Comment Period End	11/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Agency Contact:

Dr. Robert Flanders
Regulatory Coordination Specialist,
Regulatory Coordination Staff, PPQ
Department of Agriculture
Animal and Plant Health Inspection Service
Unit 141
4700 River Road
Riverdale, MD 20737-1228
Phone: 301 734-5930

RIN: 0579–AA99

USDA—Grain Inspection, Packers and Stockyards Administration (GIPSA)

PROPOSED RULE STAGE

3. ● REGULATIONS TO ENSURE MORE EQUITABLE COMPETITION IN THE LIVESTOCK AND MEAT PACKING INDUSTRIES (LIVESTOCK AND POULTRY MARKETING)

Priority:

Other Significant

Legal Authority:

7 USC 181 et seq

CFR Citation:

9 CFR 201

Legal Deadline:

None

Abstract:

GIPSA proposes adding five provisions to regulations under the Packers and Stockyards Act to address certain trade and anti-competitive practices in the livestock and poultry sectors. This series of regulations will increase transparency of market transactions and allow market participants to compete more effectively and fairly. The provisions will also facilitate the Department's investigative procedures and support more effective enforcement of the Packers and Stockyards (P&S) Act. The provisions will (1) clarify recordkeeping requirements for packers; (2) mandate disclosure of specific production contract terms in plain language; (3) prohibit restrictions on the disclosure of contract terms; (4) require that livestock owned by different people be purchased or offered for purchase on its own merits; and (5) specify conditions under which packers may offer premiums and discounts in carcass merit transactions.

Statement of Need:

1. Clarifying recordkeeping requirements for packers. Recent GIPSA investigations have shown that packers are not maintaining sufficient information to fully and correctly describe all business transactions as required by section 401 of the P&S Act. Differences also exist in the format in which packers maintain data and what data they maintain, including when a transaction begins and ends.

2. Mandate disclosure of specific production contract terms in plain language. Production contracts often are written in such a way that producers are unable to determine the basic requirements and terms of the contracts. The need to disclose certain contract terms is important to ensure that both parties to a contract understand the terms of the contract (the concept of disclosure of certain terms of contracts has been well established in lending and real estate transactions). Failure to disclose contract terms in plain language may be an unfair trade practice because without plain language disclosure, the contracts may be misleading or deceptive to producers and therefore may impede market efficiency.

3. Prohibit restrictions on the disclosure of contract terms. Contracts frequently contain clauses that prohibit contracting parties from sharing information about or disclosing contract terms to others, including their attorneys and accountants. Producers have complained that such clauses have limited their ability to obtain legal or financial advice once a contract is executed.

4. Require that livestock owned by different people be purchased or offered for purchase on its own merits. Some dealers, packers, and market agencies make the purchase of one consignment or lot of livestock conditional on a purchaser's agreement to purchase another lot of livestock (typically of lower quality) being offered by another seller. These transactions, also known as string sales, result in average pricing for different qualities of livestock offered by more than one seller. Many industry observers believe that selling on averages reduces incentives for sellers to improve livestock quality and for packers to pay premiums for higher quality livestock.

5. Specify conditions under which packers may offer premiums and discounts in carcass merit transactions. Some packers purchasing livestock on a carcass merit (grade and yield) basis offer premiums or discounts (prices differences) for the same quality livestock. Prices for livestock purchased on a carcass merit basis reflect differences in animal quality. Any further differences in price may represent undue or unreasonable preferences or disadvantage unless packers provide a valid business justification for the price differences.

Summary of Legal Basis:

The Grain Inspection, Packers and Stockyards Administration is authorized to make regulations under the Packers and Stockyards Act (7 U.S.C. 181 et seq.)

Alternatives:

GIPSA considered several alternatives, including providing specifications for recordkeeping requirements and contract language. These alternatives may be too burdensome on the livestock and poultry industries. Alternatives considered in the analysis will be presented in the proposed rule(s) for public comment.

Anticipated Cost and Benefits:

Livestock producers and poultry growers are expected to benefit from these regulations. The benefits include increased transparency and efficiency in the livestock and poultry markets. Packers and live poultry dealers may incur additional costs to comply with these regulations.

Risks:

Not applicable. These regulations do not address risks related to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	02/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Agency Contact:

Sharon L. Vassiliades
Regulatory Liaison
Department of Agriculture
Grain Inspection, Packers and Stockyards Administration
Room 1647-S
1400 Independence Avenue SW
Washington, DC 20250
Phone: 202 720-1738
Fax: 202 690-2755
Email: svassili@gipsadc.usda.gov

RIN: 0580–AA72

USDA—Food and Nutrition Service (FNS)

PROPOSED RULE STAGE

4. CHILD AND ADULT CARE FOOD PROGRAM: IMPROVING MANAGEMENT AND PROGRAM INTEGRITY

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 1766; PL 103-448; PL 104-193; PL 105-336

CFR Citation:

7 CFR 226

Legal Deadline:

None

Abstract:

This rule amends the Child and Adult Care Food Program (CACFP) regulations. The changes in this rule result from the findings of State and Federal Program reviews and from audits and investigations conducted by the Office of Inspector General. This rule proposes to revise: State agency criteria for approving and renewing institution applications; program training and other operating requirements for child care institutions and facilities; State- and institution-level monitoring requirements; and criteria for terminating agreements with institutions. This rule also includes changes that are required by the Healthy Meals for Healthy Americans Act of 1994 (Pub. L. 103-448), the Personal Responsibility and Work Opportunities Reconciliation Act of 1996 (Pub. L. 104-193), and the William F. Goodling Child Nutrition Reauthorization Act of 1998 (Pub. L. 105-336).

The changes are designed to improve program operations and monitoring at the State and institution levels and, where possible, to streamline and simplify program requirements for State agencies and institutions. (95-024)

Statement of Need:

In recent years, State and Federal program reviews have found numerous cases of mismanagement, abuse, and in some instances, fraud by child care institutions and facilities in the CACFP. These reviews revealed weaknesses in management controls over program operations and examples of regulatory noncompliance by institutions, including failure to pay facilities or failure to pay them in a timely manner; improper use of program funds for non-program expenditures; and improper meal reimbursements due to incorrect meal counts or to mis-categtorized or incomplete income eligibility statements. In addition, audits and investigations conducted by the Office of Inspector General (OIG) have raised serious concerns regarding the adequacy of financial and administrative controls in CACFP. Based on its findings, OIG recommended changes to CACFP review requirements and management controls.

Summary of Legal Basis:

Most of the changes proposed in the rule are discretionary changes being made in response to deficiencies found in program reviews and OIG audits. Other proposed changes codify statutory changes made by the Healthy Meals for Healthy Americans Act of 1994 (Pub. L. 103-448), the Personal Responsibility and Work Opportunities Reconciliation Act of 1996 (Pub. L. 104-193), and the William F. Goodling Child Nutrition Reauthorization Act of 1998 (Pub. L. 105-336).

Alternatives:

In developing the proposal, the Agency considered various alternatives to minimize burden on State agencies and institutions while ensuring effective program operation. Key areas in which alternatives were considered include State agency reviews of institutions and sponsoring organization oversight of day care homes.

Anticipated Cost and Benefits:

This rule contains changes designed to improve management and financial integrity in the CACFP. When implemented, these changes would affect all entities in CACFP, from USDA to participating children and children's households. These changes will primarily affect the procedures used by State agencies in reviewing applications submitted by, and monitoring the performance of, institutions which are participating or wish to participate in the CACFP. Those proposed changes which would affect institutions and facilities will not, in the aggregate, have a significant economic impact.

Data on CACFP integrity is limited, despite numerous OIG reports on individual institutions and facilities that have been deficient in CACFP management. While program reviews and OIG reports clearly illustrate that there are weaknesses in parts of the program regulations and that there have been weaknesses in oversight, neither program reviews, OIG reports, nor any other data sources illustrate the prevalence and magnitude of CACFP fraud and abuse. This lack of information precludes USDA from estimating the amount of money lost due to fraud and abuse or the reduction in fraud and abuse the changes in this rule will realize.

Risks:

Continuing to operate the CACFP under existing provisions of the regulations that do not sufficiently protect against fraud and abuse in CACFP puts the program at significant risk. This rule includes changes designed to strengthen current program regulations to reduce the risk associated with the program.

Timetable:

Action	Date	FR Cite
NPRM	09/12/00	65 FR 55103
NPRM Comment Period End	12/11/00	
Final Action	05/00/01	
Final Action Effective	06/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Organizations

Government Levels Affected:

State, Local

Agency Contact:

Sheri Ackerman
Agency Regulatory Officer
Department of Agriculture
Food and Nutrition Service
Room 910
3101 Park Center Drive
Alexandria, VA 22302
Phone: 703 305-2246
Email: sheri.ackerman@fns.usda.gov

RIN: 0584–AC24

USDA—FNS

5. SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN (WIC): REVISIONS IN THE WIC FOOD PACKAGES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1786

CFR Citation:

7 CFR 246

Legal Deadline:

None

Abstract:

This proposed rule will amend regulations governing the WIC food packages to disallow low-iron WIC formulas in food packages for infants; revise the maximum monthly allowances and minimum requirements for certain WIC foods; revise the substitution rates for certain WIC foods and allow additional foods as alternatives; make technical adjustments in all of the food packages to accommodate newer packaging and physical forms of the WIC foods; add vegetables as a food category in Food Packages III-VII for women and children; require that State agencies make available the full maximum foods allowed in each package; revise the criteria for developing State agency proposals for alternative food packages to accommodate participant food preferences more effectively; revise the purpose, content, and requirements for Food Package III; and address general provisions that apply to all the food packages. These revisions will improve the likelihood that WIC recipients achieve the food servings recommendations of the Dietary Guidelines for Americans and nutritional recommendations, providing WIC participants with a wider variety of foods, accommodating newer packaging and physical forms of WIC foods, and providing WIC State agencies with greater flexibility in prescribing food packages, especially to accommodate participants with hardships or cultural/food preferences. (99-006)

Statement of Need:

While WIC has been successful in many areas, obesity and inappropriate dietary patterns have become equal, if not greater, problems for many in WIC's target population. WIC food packages and nutrition education are the chief means by which WIC affects the dietary quality and habits of participants. Results of a recent WIC study found that the supplemental food package is consistently ranked by pregnant and postpartum women as the leading positive attribute of the program. Therefore, revised food packages, which will foster greater consistency with the Dietary Guidelines for Americans, are an appropriate response to further increase the positive effects of the program among the WIC eligible population.

The overarching objective of this rule is to improve disease prevention and nutritional status by improving dietary quality and nutritional adequacy of the WIC food packages by:

1. Improving the manner in which the nutrients lacking in the target population's diet are provided by revising food packages to reflect more closely the Dietary Guidelines for Americans as represented by the diet recommendations of the Food Guide Pyramid; and

2. Increasing the nutritional adequacy of the WIC food packages for medically needy participants by providing a large proportion of the Recommended Energy Allowances (REA) and Recommended Dietary Allowances (RDA) under the revised Food Package III, which is generally comprised of special nutritional formulas for this extremely vulnerable group.

Summary of Legal Basis:

The WIC Program was established to provide nutritious supplemental foods, nutrition education, and referrals to related health and social services to low-income pregnant, breastfeeding and non-breastfeeding postpartum women, infants, and children up to age 5. Section 17 of the Child Nutrition Act of 1966 (as amended, 42 USC 1786) clearly established the WIC Program as a supplemental nutrition program designed to provide nutrients determined by nutritional research to be lacking in the diets of the WIC target population. WIC law requires that, to the extent possible, the fat, sugar, and salt content of WIC foods be appropriate. The law gives substantial latitude to the Department in designing WIC food offerings but obligates the Department to prescribe foods that effectively and economically supply the target nutrients.

Alternatives:

The Food and Nutrition Service (FNS) has based its decisions to propose certain changes in the WIC food packages on several considerations, such as nutritional benefit to WIC participants in terms of meeting their dietary needs more effectively, nutrient density in terms of the WIC target nutrients and/or other nutrients of concern to the WIC population, versatility in terms of meal planning or food preparation, year-round availability, broad participant appeal, cost impact, WIC agency administrative manageability, and the supplemental nature of the WIC food packages. Overall, the selection of changes FNS is proposing are among those most frequently requested by WIC agencies and participants. FNS also believes that these changes will have the most positive impact on improving the nutritional integrity of the food packages considering the associated costs.

Anticipated Cost and Benefits:

The revisions of the WIC food packages, apart from the revisions to Food Package III for medically needy participants, have been analyzed as a group for the purposes of cost-effectiveness because together they attain the overall goal of improving dietary patterns and offering alternatives to meet dietary needs. These changes would help participants achieve dietary patterns that are more consistent with the Dietary Guidelines for Americans. The changes include the addition of vegetables; the reduction of fluid milk, cheese, juice, and powdered formula; the substitution of canned beans for dried beans and soy-based beverages for fluid milk; and small changes in the evaporated milk reconstitution rate and the maximum allowance for eggs. In addition, these changes must be viewed as a group because available research on cost-effectiveness and cost/benefit analysis of diet tend to focus on the dietary pattern as a whole.

As proposed, these changes would save the WIC Program a total of $77 million in the first year. The cost-effectiveness

of achieving food packages which are more balanced, lower in fat, and which provide alternatives to people with food intolerances, cultural preferences, and certain hardships is significant. Achieving the intended outcomes through these food package changes is extremely cost-effective as they are achieved at a net savings of approximately $10.45 per year for every WIC participant whose food package and diet are improved by the changes.

The benefits from changes in the food package for medically needy WIC participants (Food Package III) come in the form of avoided medical interventions such as moving from less expensive enteral feeding methods to more expensive parental feeding (ADA, 1995), hospitalization, or surgery. FNS cannot determine the number or seriousness of the interventions that may be averted by this rule. However, it is constructive to consider the size of the increases in the maximum allowances, and thus the additional proportion of medically fragile participants' dietary needs that the revised rule will provide and ensure. The increases in maximum allowances of medical formulas of up to 188 percent for women and children are achieved at a cost of between $21 and $95 million, or between $362 and $1639 per medically needy woman and child, per year. The increases of up to 63 percent for infants are achieved at a cost of between $44 and $75 million, or between $584 and $996 per medically needy infant, per year.

The net cost/savings, including medical foods and other changes, is estimated to range from -7 million to +94 million the first year, with 5-year totals ranging from -30 million to +501 million.

Risks:

This rule is intended to improve the nutritional status and dietary patterns of the WIC target population, as a response to the threat of increasing risk factors for nutrition-related diseases—obesity, diabetes, coronary heart disease, stroke, and cancer, to name a few—in the WIC eligible population.

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	
NPRM Comment Period End	01/00/01	
Final Action	09/00/01	
Final Action Effective	11/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State, Local, Tribal, Federal

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Sheri Ackerman
Agency Regulatory Officer
Department of Agriculture
Food and Nutrition Service
Room 910
3101 Park Center Drive
Alexandria, VA 22302
Phone: 703 305-2246
Email: sheri.ackerman@fns.usda.gov

RIN: 0584–AC90

USDA—FNS

FINAL RULE STAGE

6. SPECIAL SUPPLEMENTAL FOOD PROGRAM FOR WOMEN, INFANTS, AND CHILDREN (WIC): FOOD DELIVERY SYSTEMS

Priority:

Other Significant

Legal Authority:

42 USC 1786

CFR Citation:

7 CFR 246

Legal Deadline:

NPRM, Statutory, March 1, 1999.

Final, Statutory, March 31, 2000.

Abstract:

A proposed rule addressing WIC Food Delivery Systems was published on December 28, 1990 (55 FR 53446). The Department provided a 120-day comment period for the proposed rule, which closed on April 28, 1991. Nearly 1,100 comments were received from a wide variety of sources. Despite the degree of preliminary input to the December 28, 1990, proposed rule, many of the commenters responding during the formal comment period suggested that the Department's food delivery regulations be proposed again, rather than proceeding directly to a final rule. In addition, several members of Congress requested that the rule be reproposed in light of its impact on State agency food delivery systems. On June 16, 1999, the Department issued a second proposed rule addressing WIC food delivery systems and requirements. This second rule addresses many of the provisions contained in the previous rulemaking and contains modifications to some of the proposed provisions, as well as clarifications of several provisions that may not have been clearly understood in the earlier rule. See also RIN 0584-AC50 for related provisions that fulfill the statutory deadline.

Statement of Need:

On December 28, 1990, the Department published a proposed rule designed primarily to strengthen State agency operations in vendor management and related food delivery areas for the WIC Program. This proposal was developed with input over several years' time from State agency experts in food delivery and with the full support of and encouragement from Congress and the Department's Office of Inspector General (OIG). The Department provided a 120-day comment period for the proposed rule, which closed on April 28, 1991. During this comment period, nearly 1,100 comments were received from State and local WIC agencies, vendors, and associated groups, public interest groups, members of Congress, members of the public, and WIC participants.

Despite the degree of preliminary input to the December 28, 1990, proposed rule, many of the commenters suggested that the Department's food delivery regulations needed to be proposed again, rather than proceeding directly to a final rule. In addition, several members of Congress requested that the rule be reproposed in light of its impact on State agency food delivery systems.

The Department has therefore issued a second proposed rule addressing WIC food delivery systems integrity and procedural requirements. This second rule addresses many of the provisions contained in the previous rulemaking and contains significant modifications to some of the proposed revisions, as well as clarifications to a number of provisions that may not have been clearly understood in the earlier rule. The rule is intended to provide for more cost effective and efficient management of WIC vendors by State agencies. The Department provided a 120-day public comment period for this proposed rule. The Department intends to publish a final rule, based on all of the comments received, by the end of calendar year 2000.

Although this rule does not have a direct impact on reducing risks to public health, safety, or the environment, it will significantly improve the operation and accountability of the WIC Program nationwide.

Alternatives:

Given the intensive input that has been gathered for the development of this rule since it was recommended by the General Accounting Office in 1988 and the comments that were received pertaining to the first proposed version of the rule in December 1990, the Department has determined that there were no viable alternatives to the provisions included in the reproposal. The alternative of proceeding directly to promulgation of a final rule based on the 1990 proposal has been rejected by Congress.

Anticipated Cost and Benefits:

The costs of this action include costs due to vendor overcharges and costs associated with the proposal. The estimated costs for implementation of the proposal included a shift of not more than $2.0 million in WIC Program Nutrition Services and Administration (NSA) funds within the 87 State agencies, partially from reduced requirements for management evaluations of local agencies and reduced costs due to elimination of representative on-site monitoring. They also include $0.5 million in additional costs to vendors to meet the proposed minimum training and authorization requirements. It should be noted that all the vendors are currently required to participate in some type of training and complete an application form for program authorization. The estimated $0.5 million in additional costs therefore represents those instances where current training and authorization requirements are below the level established in the proposal. In these instances, vendors may incur costs in attending more frequent training sessions or may be required to complete an application form at more frequent intervals. The estimated cost does not represent charges to the vendor for training or authorization. Rather, the cost represents the estimated cost of the vendor's time to participate in the training session and to complete the application form.

The gross benefit results from a significant reduction in vendor overcharges. A significant net benefit of $37 million is expected, as vendor overcharges are estimated at $39.5 million and costs associated with the proposal are a maximum of $2.5 million.

Risks:

This rule is intended to ensure greater program accountability and efficiency in food delivery and related areas and to promote a decrease in vendor violations of program requirements and loss of program funds.

Timetable:

Action	Date	FR Cite
NPRM	06/16/99	64 FR 32308
NPRM Comment Period End	10/14/99	64 FR 32308
Final Action	10/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State, Local, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Sheri Ackerman
Agency Regulatory Officer
Department of Agriculture
Food and Nutrition Service
Room 910
3101 Park Center Drive
Alexandria, VA 22302
Phone: 703 305-2246
Email: sheri.ackerman@fns.usda.gov

RIN: 0584–AA80

USDA—FNS

7. FOOD STAMP PROGRAM: REVISIONS TO THE RETAIL FOOD STORE DEFINITION AND PROGRAM AUTHORIZATION GUIDANCE

Priority:

Other Significant

Legal Authority:

PL 103-225; 7 USC 2012; 7 USC 2018

CFR Citation:

7 CFR 271; 7 CFR 278

Legal Deadline:

Final, Statutory, March 25, 1994.

Abstract:

This rule would implement provisions of Public Law 103-225 requiring firms to offer a variety of staple food items for sale or to have more than 50 percent of gross retail sales in staple foods. This rule also addresses the requirement in Public Law 103-225 to provide periodic notices to participating firms, clarifying certain eligibility criteria. (95-003)

Statement of Need:

Public Law 103-225 amends the Food Stamp Act of 1977 to make changes in eligibility requirements for retail food stores to participate in the Food Stamp Program. Prior to enactment of these changes, a retail food store qualified to participate in the Food Stamp Program if more than 50 percent of its total eligible food sales were in staple foods. The new law changes that to require 50 percent of its total gross sales in staple foods. It also provides another option for stores not meeting the new 50 percent rule. Those stores can now qualify if they offer for sale, on a continuous basis, a variety of food in each of four categories of staple foods. The staple food categories are defined as ''(1) meat, poultry, or fish; (2) bread or cereals; (3) vegetables or fruits; or (4) dairy products.'' This statutory change in eligibility will require developing policy definitions for the terms ''continuous basis,'' ''variety,'' and ''perishable.''

Alternatives:

None. The new law also requires the Secretary to issue new rules providing for the periodic reauthorization of retail food stores and wholesale food concerns. This must include providing periodic notice of the definitions for ''retail food stores,'' ''staple foods,'' and ''perishable foods.''

Anticipated Cost and Benefits:

It is not anticipated that this rule will impact program costs. It is anticipated that the clarifications of program eligibility criteria in this rule will make it easier for firms to understand and for the Food and Nutrition Service to administer.

Timetable:

Action	Date	FR Cite
NPRM	06/30/99	64 FR 35082
NPRM Comment Period End	08/30/99	64 FR 35082
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

Sheri Ackerman
Agency Regulatory Officer
Department of Agriculture
Food and Nutrition Service
Room 910
3101 Park Center Drive
Alexandria, VA 22302
Phone: 703 305-2246
Email: sheri.ackerman@fns.usda.gov

RIN: 0584–AB90

USDA—FNS

8. FSP: PERSONAL RESPONSIBILITY PROVISIONS OF THE PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT OF 1996

Priority:

Economically Significant. Major under 5 USC 801.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

PL 104-193

CFR Citation:

7 CFR 271; 7 CFR 272; 7 CFR 273

Legal Deadline:

Other, Statutory, August 22, 1996, for PL 104-193 sec 813, 814, 820, 821, 837, and 911.

Other, Statutory, November 22, 1996, for PL 104-193 sec 824.

Other, Statutory, July 1, 1997, for PL 104-193 sec 115.

Abstract:

This rule will implement 13 provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. (96-019)

Statement of Need:

Public Law 104-193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, amends the Food Stamp Act of 1977, to add some new eligibility requirements and disqualifiers and increase some existing penalties for noncompliance with food stamp rules. The new law: (1) Makes individuals convicted of drug-related felonies ineligible for food stamps; (2) doubles the penalties for violating food stamp program requirements; (3) permanently disqualifies individuals convicted of trafficking in food stamp benefits of $500 or more; (4) allows States to disqualify an individual from food stamps if the individual is disqualified from another means-tested program for failure to perform an action required by that program; (5) makes individuals ineligible for 10 years if they misrepresent their identity or residence in order to receive multiple food stamp benefits; (6) makes fleeing felons and probation and parole violators ineligible for the food stamp program; (7) allows States to require food stamp recipients to cooperate with child support agencies as a condition of food stamp eligibility; (8) allows States to disqualify individuals who are in arrears in court-ordered child support payments; (9) limits the food stamp participation of most able-bodied adults without dependents to 3 months in a 3-year period during times the individual is not working or participating in a work program; (10) prohibits an increase in food stamp benefits when households' income is reduced because of a penalty imposed under a Federal, State, or local means-tested public assistance program for failure to perform a required action; (11) requires States to provide households' addresses, social security numbers, or photographs to law enforcement officers to assist them in locating fugitive felons or probation or parole violators; (12) prohibits an increase in food stamp benefits when households' income is reduced because of a penalty imposed under a Federal, State, or local means-tested public assistance program for an act of fraud by the individual under the program; and (13) clarifies that States may not impose a separate food stamp sanction on individuals who are disqualified from TANF for failure to send their children to school or failure to attain a high school diploma or a GED.

Summary of Legal Basis:

All of the provisions of this rule are mandated by Public Law 104-193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Alternatives:

None.

Anticipated Cost and Benefits:

Over 5 years, the provisions are expected to reduce the cost of the Food Stamp Program by approximately $1.81 billion.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/17/99	64 FR 70920
NPRM Comment Period End	02/15/00	
Final Action	10/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, State, Local

Agency Contact:

Sheri Ackerman
Agency Regulatory Officer
Department of Agriculture
Food and Nutrition Service
Room 910
3101 Park Center Drive
Alexandria, VA 22302
Phone: 703 305-2246
Email: sheri.ackerman@fns.usda.gov

RIN: 0584–AC39

USDA—FNS

9. FSP: NONCITIZEN ELIGIBILITY AND CERTIFICATION PROVISIONS OF PUBLIC LAW 104-193 (PREVIOUSLY ENTITLED STATE FLEXIBILITY AND CERTIFICATION PROVISIONS)

Priority:

Economically Significant. Major under 5 USC 801.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

PL 104-193; PL 104-208; 7 USC 2011 to 2032

CFR Citation:

7 CFR 272.3; 7 CFR 273.11(e); 7 CFR 273.11(j); 7 CFR 273.13; 7 CFR 273.14(b); 7 CFR 273.14(e); 7 CFR 273.1; 7 CFR 273.2; 7 CFR 273.4; 7 CFR 273.9(c); 7 CFR 273.9(d); 7 CFR 273.10(a); 7 CFR 273.10(c) to 273.10(f); 7 CFR 273.11(a) to 273.11(c)

Legal Deadline:

Other, Statutory, August 22, 1996, for PL 104-193 sec 813, 814, 820, 821, 837, and 911.

Other, Statutory, November 22, 1996, for PL 104-193 sec 824.

Other, Statutory, July 1, 1997, for PL 104-193 sec 115.

For provisions effective upon enactment, the statutory implementation date is August 22, 1996.

Abstract:

This rule proposes to amend Food Stamp Program regulations to implement 14 provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 and one provision of the Omnibus Consolidated Appropriations Act of 1996. These provisions would increase State agency flexibility in processing applications for the Food Stamp Program and allow greater use of standard amounts for determining deductions and self-employment expenses. The provisions would also give State agencies options to issue partial allotments for households in treatment centers, issue combined allotments to certain expedited service households, and certify elderly or disabled households for 24 months. Other changes would revise requirements for determining noncitizen eligibility and the eligibility and benefits of sponsored noncitizens, eliminate the exclusion of certain transitional housing payments and State and local energy assistance, exclude the earnings of students under 18, and require proration of benefits following any break in certification. The rule would also add vehicles to the assets which may be covered under the inaccessible resources provisions of the Food Stamp Act of 1977. (96-020)

Statement of Need:

This action is required by Public Law 104-193, Public Law 104-208, Public Law 105-53, and Public Law 105-185.

Summary of Legal Basis:

This rule is required to implement the provisions of sections 402, 421, 801, 807, 808, 809, 811, 812, 818, 827, 828, 830, and 835 of Public Law 104-193; section 552 of Public Law 104-208; sections 5302, 5305, 5306, 5562, 5563, 5571, 5572, and 5573 of Public Law 105-53; and section 503 of Public Law 105-185.

Anticipated Cost and Benefits:

The provision of this rule would reduce Food Stamp Program costs for FY 1997-2002 by approximately $6.605 billion.

Timetable:

Action	Date	FR Cite
NPRM	02/29/00	65 FR 10856
NPRM Comment Period End	05/01/00	
Final Action	10/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, State, Local

Agency Contact:

Sheri Ackerman
Agency Regulatory Officer
Department of Agriculture
Food and Nutrition Service
Room 910
3101 Park Center Drive
Alexandria, VA 22302
Phone: 703 305-2246
Email: sheri.ackerman@fns.usda.gov

RIN: 0584–AC40

USDA—FNS

10. FSP: NONDISCRETIONARY PROVISIONS OF THE PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT OF 1996

Priority:

Economically Significant. Major under 5 USC 801.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

PL 104-193, sec 803; PL 104-193, sec 804; PL 104-193, sec 805; PL 104-193, sec 809; PL 104-193, sec 810; PL 104-193, sec 838; PL 104-193, sec 109; PL 104-193, sec 826

CFR Citation:

7 CFR 271.2; 7 CFR 273.1; 7 CFR 273.2; 7 CFR 273.8; 7 CFR 273.9; 7 CFR 273.10; 7 CFR 276.2(e)

Legal Deadline:

Other, Statutory, August 22, 1996, for PL 104-193 sec 803, 805 and 838.

Other, Statutory, October 1, 1996, for PL 104-193 sec 804 and 810.

Other, Statutory, January 1, 1997, for PL 104-193 sec 809.

For provisions effective upon enactment, the statutory implementation date is August 22, 1996.

Abstract:

This final rule amends the Food Stamp Program regulations to implement eight provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. These provisions require no interpretation or discretion: 1) Freeze the minimum allotment at $10; 2) change the way the maximum allotments are calculated to use 100 percent of the Thrifty Food Plan as opposed to 103 percent; 3) freeze the standard deduction at current level and eliminate the adjustment procedures; 4) cap the excess shelter expense deduction; 5) change the household composition definition so that children under 22 years of age and living with their parents cannot be a separate household; 6) increase the timeframe from 5 to 7 days for expedited service; 7) set a time limit of not more than 90 days living in another person's house for considering a person homeless; and 8) set the fair market value of vehicles at $4,600 through 9/30/96 and raise it to $4,650 effective 10/1/96 and eliminate future adjustments. (96-021)

Statement of Need:

This action is required by Public Law 104-193.

Summary of Legal Basis:

This rule is required to implement the provisions of sections 109, 803, 804, 805, 809, 810, 826, and 838 of Public Law 104-193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

Alternatives:

None. The provisions are mandated by statute.

Anticipated Cost and Benefits:

The provisions of this rule would reduce Food Stamp Program costs for FY 1997-2002 by $11.2 billion.

Timetable:

Action	Date	FR Cite
NPRM	07/12/99	64 FR 37454
NPRM Comment Period End	09/10/99	
Final Action	10/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

State, Local

Agency Contact:

Sheri Ackerman
Agency Regulatory Officer
Department of Agriculture
Food and Nutrition Service
Room 910
3101 Park Center Drive
Alexandria, VA 22302
Phone: 703 305-2246
Email: sheri.ackerman@fns.usda.gov

RIN: 0584–AC41

USDA—FNS

11. FOOD STAMP PROGRAM: WORK PROVISIONS OF THE PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT OF 1996 AND THE FOOD STAMP PROVISIONS OF THE BALANCED BUDGET ACT OF 1997

Priority:

Other Significant

Legal Authority:

PL 104-193

CFR Citation:

7 CFR 273.7; 7 CFR 273.22

Legal Deadline:

None

Abstract:

This proposed rule will implement revisions to the Food Stamp Program's work and employment and training requirements, as well as new provisions for a work supplementation or support program and an employment initiative program. (96-025)

Statement of Need:

This rule is necessary to implement revisions to the Food Stamp Program's work requirements.

Summary of Legal Basis:

All provisions of this proposed rule are mandated by Public Law 104-193 and the Balanced Budget Act of 1997.

Alternatives:

The alternative is not to revise current rules. This is not practical. The current rules have been superseded by changes brought about by Public Law 104-193.

Anticipated Cost and Benefits:

Federal costs will increase by $1.4 billion between fiscal year 1997 and fiscal year 2002. State agencies will benefit by achieving greater flexibility to encourage work and foster personal responsibility and independence.

Risks:

An increase in food stamp rolls would result by not implementing this rule.

Timetable:

Action	Date	FR Cite
NPRM	12/23/99	64 FR 72196
NPRM Comment Period End	02/22/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

State, Local

Agency Contact:

Sheri Ackerman
Agency Regulatory Officer
Department of Agriculture
Food and Nutrition Service
Room 910
3101 Park Center Drive
Alexandria, VA 22302
Phone: 703 305-2246
Email: sheri.ackerman@fns.usda.gov

RIN: 0584–AC45

USDA—Food Safety and Inspection Service (FSIS)

PROPOSED RULE STAGE

12. PERFORMANCE STANDARDS FOR READY-TO-EAT MEAT AND POULTRY PRODUCTS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

21 USC 451 et seq; 21 USC 601 et seq

CFR Citation:

9 CFR 317; 9 CFR 381; 9 CFR 430

Legal Deadline:

None

Abstract:

FSIS is proposing to establish pathogen reduction performance standards for all ready-to-eat meat and poultry products. The performance standards spell out the objective level of pathogen reduction that establishments must meet during their operations in order to produce safe products but allow the use of customized, plant-specific processing procedures other than those prescribed in the earlier regulations. Along with HACCP, food safety performance standards will give establishments the incentive and flexibility to adopt innovative, science-based food safety processing procedures and controls, while providing objective, measurable standards that can be verified by Agency inspectional oversight. This set of performance standards will include and be consistent with those already in place for certain ready-to-eat meat and poultry products. FSIS also is proposing testing and labeling requirements intended to reduce the incidence of Listeria in ready-to-eat meat and poultry products.

Statement of Need:

This proposed action is compelled by recent outbreaks of foodborne illness related to the consumption of adulterated ready-to-eat meat and poultry products, as well as the need to provide objective, measurable pathogen reduction standards that can be met by official establishments and compliance with which can be established through Agency inspection. Although FSIS routinely samples and tests some ready-to-eat products for the presence of pathogens prior to distribution, there are no specific regulatory performance standards for most of these products. The proposed performance standards will help ensure the safety of these products; give establishments the incentive and flexibility to adopt innovative, science-based food safety processing procedures and controls; and provide objective, measurable standards that can be verified by Agency oversight.

Summary of Legal Basis:

This action is authorized by the Federal Meat Inspection Act (21 USC 601 et seq.) and the Poultry Product Inspection Act (21 USC 45 et seq.). Exercise of the Secretary of Agriculture's function under these laws has been delegated to the Under Secretary for Food Safety (7 CFR 2.18) and by the Under Secretary to the Administrator of FSIS (7 CFR 2.53).

Alternatives:

No action.

Anticipated Cost and Benefits:

This regulation may require producers to incur additional operating costs, mostly to meet labeling, testing, and performance standard validation requirements of the proposed rule. Some of these potential costs are one-

time costs incurred in the first year and consists mostly of validation costs and expenses incurred to remedy Listeria-related problems. Recuring costs would be for increased testing, labeling, and product treatment.

FSIS estimate benefits accruing from this action will be based on the reduction in annual cases of listeriosis that should result from the proposed testing and labeling requirements.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Agency Contact:

Daniel L. Engeljohn
Director, Regulations Development and Analysis Division
Department of Agriculture
Food Safety and Inspection Service
Washington, DC 20250
Phone: 202 720-5276

RIN: 0583–AC46

USDA—FSIS

13. SHELL EGG AND EGG PRODUCTS INSPECTION REGULATIONS

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

21 USC 1031-1056

CFR Citation:

9 CFR 590.570; 9 CFR 590.575; 9 CFR 590.146; 9 CFR 590.10; 9 CFR 590.411; 9 CFR 590.502; 9 CFR 590.504; 9 CFR 590.580; 9 CFR 591; ...

Legal Deadline:

None

Abstract:

The Food Safety and Inspection Service (FSIS) is proposing to require shell egg packers and egg products plants to develop and implement Hazard Analysis and Critical Control Points (HACCP) systems and Sanitation Standard Operating Procedures (SOPs). FSIS also is proposing pathogen reduction performance standards that would be applicable to pasteurized shell eggs and egg products. Plants would be expected to develop HACCP systems that ensure products meet the pathogen reduction performance standards. Finally, FSIS is proposing to amend the Federal egg and egg products inspection regulations by removing current requirements for prior approval by FSIS of egg products plant drawings, specifications, and equipment prior to their use in official plants. The Agency also plans to eliminate the prior label approval system for egg products.

The actions being proposed are part of FSIS's regulatory reform effort to improve FSIS's egg and egg products food safety regulations, better define the roles of Government and the regulated industry, encourage innovations that will improve food safety, remove unnecessary regulatory burdens on inspected egg products plants, and make the egg and egg products regulations as consistent as possible with the Agency's meat and poultry products regulations. FSIS is also taking these actions in light of changing inspection priorities and recent findings of salmonella in pasteurized egg products.

Statement of Need:

The actions being proposed are part of FSIS's regulatory reform effort to improve FSIS's egg and egg products food safety regulations, better define the roles of Government and the regulated industry, encourage innovations that will improve food safety, remove unnecessary regulatory burdens on inspected egg products plants, and make the egg and egg products regulations as consistent as possible with the Agency's meat and poultry products regulations. FSIS is also taking these actions in light of changing inspection priorities and recent findings of salmonella in pasteurized egg products.

Summary of Legal Basis:

This rulemaking is proposed under the authority of the Egg Products Inspection Act, as amended, 21 U.S.C. 1031-1056.

Alternatives:

FSIS is engaged in a thorough review of its current regulations and, where possible, will eliminate overly prescriptive regulations and replace them with regulations that embody performance standards. Performance standards establish requirements in terms of the objective to be achieved. They specify, the ends, but do not detail the means to achieve those ends. Performance standards allow food processing establishments to develop and employ innovative and more effective sanitation or processing procedures customized to the nature and volume of their production.

To address hazards that can be presented by shell eggs and processed egg products, FSIS now is considering (1) requiring all shell egg packers and egg products plants to develop, adopt, and implement written Sanitation SOPs and HACCP plans and (2) converting to a lethality-based pathogen reduction performance standard many of the current highly prescriptive egg products processing requirements. The implementation of HACCP and Sanitation SOP requirements by shell egg packers and egg products plants would reduce the occurrence and numbers of pathogenic microorganisms in egg products. FSIS inspection program personnel would be better able to ensure that shell egg packers and egg products processing plants have the flexibility needed to properly implement HACCP and Sanitation SOPs and encourage innovation in shell egg and egg products processing.

The Agency will also propose to require that shell egg packers and egg products plants adopt sanitation SOP and HACCP plans. Plants will have significant latitude in identifying the Sanitation SOP and HACCP plan suitable for their process. The egg products industry has indicated its desire to adopt HACCP on an industry-wide basis. About 30 percent of egg products plants have already implemented HACCP or HACCP-like programs. The pathogen reduction performance standard that egg product plants will have to achieve under their HACCP plans would likely have a more economically significant impact than the requirement of Sanitation SOPs or HACCP plans.

Anticipated Cost and Benefits:

Costs

The expected costs of the proposal will depend on a number of factors, including the following:

Required Lethality. The level of lethality required in the pathogen reduction performance standard will have a significant impact on the cost of the proposal. The expected type of performance standard may specify a uniform level of pathogen reduction for a target organism. Alternatively, different reduction levels may be specified for white, yolk, and whole egg products, or production processes, reflecting the relative level of risk. As the level of lethality increases, the ability to utilize the egg for different products and formulations is diminished. The Agency will investigate the level of lethality that provides an acceptable balance between risk and egg utilization.

HACCP and Sanitation Standard Operating Procedures. Implementing a HACCP plan and Sanitation SOPs requires the preparation of a plan, employee training, documentation and recordkeeping, and testing procedures. The costs associated with HACCP implementation are reduced by the extent to which quality assurance or similar programs are utilized by shell egg packers and egg products firms and the availability of off-the-shelf HACCP plans. The types of Sanitation SOPs being considered are essentially the same as those for meat and poultry, and costs would be similar.

Plant Compliance/Enforcement. FSIS costs for monitoring and enforcement are expected to be lower than those for current comparable activities as the program moves from continuous inspection (inspector on duty throughout the entire shift) to eventually being monitored on a patrol assignment. We are not aware of any estimates of FSIS costs for verifying process control and pathogen reduction for egg products. They would probably be similar in costs to those for meat and poultry inspection. The monitoring costs for some plants may increase, especially those reliant on the inspector to be the quality control expert.

Benefits

The types of potential benefits associated with this rule are: Improvements in human health due to pathogen reduction; improved utilization of FSIS inspection program resources; and cost savings resulting from the flexibility of egg products plants in achieving a lethality-based pathogen reduction performance standard. Once specific alternatives are identified, economic analysis will identify the quantitative and qualitative benefits associated with each.

Human health benefits are based on changes from a baseline level of illnesses and the health cost per illness. FSIS egg products testing results indicate either some pasteurization processes are inadequate, or that egg products are being contaminated with salmonella after pasteurization, prior to, or during packaging. The results indicate a very low level of contamination. Pasteurized egg products have not been identified/associated with any known outbreaks; however, unpasteurized egg products have been implicated in foodborne outbreaks. Salmonella would principally be found in unpasteurized product. However, there have been a few instances when SE has been isolated from egg products found to be positive for the presence of salmonella. In the majority of these cases, the salmonella contamination can be attributed to post-pasteurization product contamination. Sanitation SOP and HACCP requirements could remedy this problem by enhancing the effectiveness of pasteurization by minimizing microbiological hazards before and after pasteurization.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

None

Agency Contact:

Daniel L. Engeljohn
Director, Regulations Development and Analysis Division
Department of Agriculture
Food Safety and Inspection Service
Washington, DC 20250
Phone: 202 720-5276

RIN: 0583–AC58

USDA—FSIS

14. NUTRITION LABELING OF GROUND OR CHOPPED MEAT AND POULTRY PRODUCTS AND SINGLE-INGREDIENT PRODUCTS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

21 USC 601 et seq; 21 USC 451 et seq

CFR Citation:

9 CFR 317; 9 CFR 381

Legal Deadline:

None

Abstract:

FSIS is proposing to amend the Federal meat and poultry products inspection regulations to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products. The Agency is proposing to require that nutrition information be provided for these products either on their label or at their point-of-purchase. FSIS is proposing to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products because during the most recent surveys of retailers, the Agency did not find significant participation in the voluntary nutrition labeling program for single-ingredient, raw meat and poultry products.

In this proposed rule, FSIS is also proposing to amend its regulations to extend mandatory labeling to single-ingredient ground or chopped products. Under this proposal, individual retail packages of ground or chopped meat and ground or chopped poultry products would bear nutrition labeling. The Agency has determined that ground or chopped products are different from other single-ingredient products in several important respects. Thus, FSIS is proposing to make nutrition labeling requirements for ground or chopped products consistent with those for multi-ingredient products.

Finally, FSIS is proposing to amend the nutrition labeling regulations to provide that when a ground or chopped product does not meet the criteria to be labeled ''low fat,'' a lean percentage claim may be included on the product label as long as a statement of the fat percentage also is displayed on the label.

Statement of Need:

The Agency is proposing to require that nutrition information be provided for the major cuts of single-ingredient, raw meat and poultry products, either on their label or at their point-of-purchase, because during the most recent surveys of retailers, the Agency did not find significant participation in the voluntary nutrition labeling program for single-ingredient, raw meat and poultry products. Without the nutrition information for the major cuts of single-

ingredient, raw meat and poultry products that would be provided if significant participation in the voluntary nutrition labeling program existed, FSIS believes that these products would be misbranded.

FSIS is also proposing to amend its regulations to require nutrition labels on the packages of all ground or chopped meat and poultry products. The Agency has determined that single-ingredient, raw ground or chopped products are different from other single-ingredient, raw products in several important respects. Thus, FSIS is proposing to make nutrition labeling requirements for all ground or chopped products consistent with those for multi-ingredient products.

Finally, FSIS is proposing to amend the nutrition labeling regulations to provide that when a ground or chopped product does not meet the criteria to be labeled ''low fat,'' a lean percentage claim may be included on the product as long as a statement of the fat percentage is also displayed on the label or in labeling. FSIS is proposing this provision because many consumers have become accustomed to this labeling on ground beef products, and because this labeling provides quick, simple, accurate means of comparing all ground or chopped meat and poultry products.

Summary of Legal Basis:

During the most recent surveys of retailers, FSIS did not find significant participation in the voluntary nutrition labeling program for single-ingredient, raw meat and poultry products. These surveys assessed whether retailers were providing nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat and poultry products sold. Without the nutrition information for the major cuts of single-ingredient, raw meat and poultry products that would be provided if significant participation in the voluntary nutrition labeling program existed, FSIS believes that these products would be misbranded under section 1(n) of the Federal Meat Inspection Act (FMIA) or section 4(h) of the Poultry Products Inspection Act (PPIA). In addition, the nutrient and fat content of single-ingredient, raw ground or chopped products varies significantly, and consumers cannot readily detect the differences in nutrient and fat content in these products. For these reasons, FSIS believes that ground or chopped meat and poultry products that do not include nutrition information would be misbranded under section 1(n) of the FMIA or section 4(h) of the PPIA.

Alternatives:

No action; nutrition labels required on all single-ingredient, raw products (major cuts and non-major cuts) and all ground or chopped products; nutrition labels required on all major cuts of single-ingredient, raw products (but not on nonmajor cuts) and all ground or chopped products; nutrition information at the point-of-purchase required for all single-ingredient, raw products (major and nonmajor cuts) and for all ground or chopped products.

Anticipated Cost and Benefits:

Costs would include the equipment for making labels, labor, and materials used for labels for ground or chopped products. FSIS believes that the cost of providing nutrition labeling for the major cuts of single-ingredient, raw meat and poultry products should be negligible. Retail establishments would have the option of providing nutrition information through point-of-purchase materials. These materials are available for a nominal fee through the Food Marketing Institute. Also, FSIS intends to make point-of-purchase materials available, free of charge, on the FSIS web site.

Benefits of the nutrition labeling rule would result from consumers modifying their diets in response to new nutrition information concerning ground or chopped products and the major cuts of single-ingredient, raw products. Reductions in consumption of fat and cholesterol are associated with reduced incidence of cancer and coronary heart disease.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Daniel L. Engeljohn
Director, Regulations Development and Analysis Division
Department of Agriculture
Food Safety and Inspection Service
Washington, DC 20250
Phone: 202 720-5276

RIN: 0583–AC60

USDA—FSIS

15. PATHOGEN REDUCTION; HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEMS; ADDITIONS TO E. COLI CRITERIA AND SALMONELLA PERFORMANCE STANDARDS

Priority:

Other Significant

Legal Authority:

21 USC 601 to 695; 21 USC 451 to 470

CFR Citation:

9 CFR 310; 9 CFR 381

Legal Deadline:

None

Abstract:

FSIS is proposing to add generic E. coli criteria and salmonella performance standards to the regulations. In addition, FSIS is proposing to revise the terms used to identify and define certain classes of product listed in the salmonella tables.

FSIS is proposing to delay making the proposed criteria and standards applicable for 1 year for small establishments and for 2 years for very small establishments.

Statement of Need:

FSIS is proposing to update its pathogen reduction (PR)/Hazard Analysis and Critical Control Point (HACCP) Systems regulations by adding generic Escherichia coli (E. coli) criteria for cattle, swine, and goose carcasses based on the sponging method of sample collection and for turkey carcasses based on the sponging and rinse methods of sample collection. FSIS is also proposing new pathogen reduction performance standards for Salmonella in cattle, swine, young turkey, and goose carcasses by the sponging method and fresh pork sausage by direct sampling. The new cattle performance standard would replace the existing Salmonella performance standards for steers/heifers and cows/bulls. The new swine

standard would replace the existing standard for hogs. These new standards apply to all market classes of cattle and swine, respectively.

In addition, FSIS is proposing to revise the terms used to identify and define certain classes of product listed in the Salmonella tables to more accurately reflect the products sampled in the baseline studies that are the basis for the standards. The Agency also intends to correct some errors in the E. coli and Salmonella tables and to change the footnotes to the tables for greater clarity.

These changes would ensure that the pathogen reduction performance standards and process control criteria applying to products and establishments regulated by FSIS are appropriate and accurate. E. coli criteria will help establishments to improve process controls for certain classes of raw product. Improved process controls will help reduce pathogens on certain raw products and may result in the reduction of foodborne illness. The provision of E. coli criteria based on the sponge method of sampling would provide affected establishments with flexibility in complying with the rule.

In addition, to the need to update and add flexibilty to existing PR/HACCP requirements, the rule is needed to help address the market failure associated with the consumer's lack of information about pathogens that may be present in certain classes of meat and poultry products and to help meet the commitments made by FSIS in its PR/HACCP and associated regulatory reform initiatives.

Summary of Legal Basis:

This rulemaking was proposed under the authorities of the Federal Meat Inspection Act, as amended (21 U.S.C. 601-695), and the Poultry Products Inspection Act, as amended (21 U.S.C. 451-470).

Alternatives:

No action.

Anticipated Cost and Benefits:

The costs of the proposal are estimated to be in the $18 million to $20 million range and are attribute to the need for some firms to modify their processes to meet the new standards.

Benefits would accrue from reductions in pathogen levels, which, in turn, might lead to reductions in foodborne illness. There is, however, a great deal of uncertainty associated with the human health benefits estimates, including data reflecting a decline in foodborne illness after implementation of the PR/HACCP regulations because of the lack of prevalence data for the period before and after implementation of the regulations.

Risks:

None.

Timetable:

Action	Date	FR Cite
Proposed Rule	03/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Sectors Affected:

None

Agency Contact:

Daniel L. Engeljohn
Director, Regulations Development and Analysis Division
Department of Agriculture
Food Safety and Inspection Service
Washington, DC 20250
Phone: 202 720-5276

RIN: 0583–AC63

USDA—FSIS

16. ● POULTRY INSPECTION: REVISION OF FINISHED PRODUCT STANDARDS WITH RESPECT TO INGESTA

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

21 USC 451-470 et seq

CFR Citation:

9 CFR 381

Legal Deadline:

None

Abstract:

FSIS is seeking to clarify its Poultry Inspection Regulations regarding visible ingesta on poultry carcasses and parts. A preliminary regulatory impact analysis conducted by FSIS determined that costs to achieve zero tolerance far outweighed benefits. This action was precipitated by a civil suit filed against USDA.

Statement of Need:

FSIS is seeking to clarify the regulations respecting visible ingesta on poultry carcasses and parts. In 1997, FSIS issued a final rule removing the process tolerance level for fecal contamination on poultry carcasses, in effect, adopting a zero process tolerance for poultry fecal matter. During the comment period on the final rule, several commenters supported a zero tolerance for ingesta. As a result, FSID solicited comments and information on ingesta to determine whether there was a need for additional regulatory measures regarding ingesta. No comments were received. Lacking any information to suggest the current tolerance standards were inadequate, FSIS let stand the current process tolerance for ingesta contamination. However, partly in view of a civil suit alleging disparate regulation of the meat and poultry industries by FSIS and challenging the existing process tolerance for ingesta contamination of poultry carcasses, FSIS is issuing an ANPRM to determine how it should proceed on this issue.

Summary of Legal Basis:

This action is authorized by the Poultry Products Inspection Act (21 U.S.C. 451 et seq.). Exercise of the Secretary of Agriculture's functions under these laws has been delegated to the Under Secretary of Food Safety (7 CFR 2.18) and by the Under Secretary to the Administrator of FSIS (7 CFR 2.53). This action also is being taken in the context of proceedings in the matter of Kenney v. Glickman.

Alternatives:

No action.

Anticipated Cost and Benefits:

FSIS is seeking information and data from the public about the costs of establishing any of several alternative tolerance levels for ingesta and the effects on operations of large and small poultry establishments. In addition, we are soliciting comments on the availability of new technology that would reduce the levels of contamination of birds and on improvements in on-farm, or ''preharvest,'' husbandry practices. FSIS is interested in having information on new research that identifies microbial hazards and determines whether or not their presence results in pathogen contamination of the poultry.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Action	Date	FR Cite
NPRM Comment Period End	02/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Daniel L. Engeljohn
Director, Regulations Development and Analysis Division
Department of Agriculture
Food Safety and Inspection Service
Washington, DC 20250
Phone: 202 720-5276

RIN: 0583–AC77

USDA—FSIS

FINAL RULE STAGE

17. RETAINED WATER IN RAW MEAT AND POULTRY PRODUCTS; POULTRY-CHILLING PERFORMANCE STANDARDS

Priority:

Economically Significant. Major under 5 USC 801.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

21 USC 451 et seq; 21 USC 601 et seq

CFR Citation:

9 CFR 317; 9 CFR 381; 9 CFR 440

Legal Deadline:

None

Abstract:

FSIS is developing a rule to limit the amount of water absorbed and retained by single-ingredient raw meat and poultry products to the amount that is unavoidable in carrying out washing or chilling procedures. Such products include immersion-chilled poultry carcasses and raw meat byproducts that are chilled in water. A requirement for raw products to bear a labeling statement on absorbed water content is being considered. However, establishments having data that demonstrate their raw products do not gain weight as a result of washing or chilling would not have to label the products with such a statement. The rule also is intended to replace the command-and-control provisions of the regulations on poultry chilling and moisture control with performance standards. This rule is intended to further the Agency's regulatory reform effort and responds to a July 23, 1997, U.S. District Court order setting aside current moisture limits for frozen, cooked, or consumer-packaged whole poultry. The labeling provisions of this rule are intended to provide consumers with additional information for making purchasing decisions.

Statement of Need:

FSIS is planning to issue regulations under which meat and poultry carcasses and parts will not be permitted to retain water unless the establishment preparing the products demonstrates, with data collected under a protocol available for FSIS review, that the water retention is an avoidable consequence of such processing. In addition, the establishment will be required to state on the product label the maximum percentage of retained water in a product. The statement could appear contiguous to the product name or elsewhere conspicuously on the label. An establishment having data demonstrating that there is no retained water in its products can choose not to label the products with the retained-water statement or to make a no-retained-water claim on the product label. FSIS will accept data generated from an approved, appropriately designed protocol to support water retention levels for multiple establishments using similar post-evisceration processing techniques and equipment.

FSIS is revising the poultry chilling regulations, including the regulation limiting moisture retention in ready-to-cook whole chickens and turkeys, which was set aside by Federal court order. The existing general requirement for establishments to minimize moisture absorption by raw poultry will remain, along with the requirement for them to furnish equipment necessary for moisture tests to be conducted on inspected product. The tables setting moisture absorption and retention limits for the various kinds and weight classes of poultry and the requirements for daily moisture testing by FSIS inspectors will be removed.

FSIS is also revising or eliminating various ''command-and-control'' requirements governing poultry chilling, including the regulations on thawing procedures and water use and reconditioning, to improve consistency with the HACCP regulations and reflect current technological capabilities and good manufacturing practice. FSIS will give affected establishments the flexibility they need to choose the most appropriate means of carrying out their HACCP plans for protecting the safety of raw product while minimizing the potential for economic adulteration.

FSIS will apply the same retained-moisture standard to both livestock and poultry carcasses and parts. Raw, single-ingredient meat and poultry products intended for use as human food will have to bear labeling indicating the amount of retained moisture they contain as a percentage of product weight. The regulations will require post-evisceration processing of livestock or poultry carcasses and parts, including washing, chilling, and draining practices, to minimize both the growth of pathogens on edible product and moisture absorption and retention by the product.

Even if FSIS accepts the data supporting a moisture retention limit higher than zero and regulates accordingly, raw products that contain more than zero percent retained moisture will have to be labeled to reflect that fact. FSIS envisions that the final rule will require the statement ''may contain up to ———— percent retained water'' or some similar statement to appear in prominent letters contiguous to the product name or elsewhere conspicuously on the product label. The labeling statement would provide additional information to consumers of raw meat and poultry products to help them in their purchasing decisions.

This rule has been prompted by longstanding industry petitions and by the Agency's need to reform its regulations to make them more consistent with its PR/HACCP regulations, in accordance with its regulatory reform agenda. A July 1997 Federal Court decision vacating the regulations in 9 CFR 381 that contain the water-retention tables for whole birds lent further impetus to this rulemaking project.

Summary of Legal Basis:

This action is authorized by the Federal Meat Inspection Act (21 USC 601 et seq.) and the Poultry Products Inspection Act (21 USC 451 et seq.).

Exercise of the Secretary of Agriculture's functions under these laws has been delegated to the Under Secretary for Food Safety (7 CFR 2.18) and by the Under Secretary to the Administrator of FSIS (7 CFR 2.53). This action also is being taken partly in response to a U.S. Court decision in the matter of Kenney v. Glickman.

Alternatives:

This rule resulted from an analysis of six alternative regulatory approaches for addressing retained water in raw meat products and poultry products. The six alternatives include: (1) No limit on retained water but mandatory labeling that identifies the percentage of retained water in the product; (2) a requirement that all establishments meet a water limit based on best available technology, with mandatory labeling to indicate any retained water; (3) a moisture limit based on best performance with existing equipment, with mandatory labeling to show any retained water; (4) a standard of zero retained moisture; (5) a requirement that no retained water could be included in net weight; and (6) a requirement of zero retained water unless the water retention is unavoidable in processes necessary to meet food safety requirements, e.g., to reduce pathogens, with product labeling to indicate the presence of retained moisture, where applicable. For all alternatives where a limit on retained water is established, the analysis assumed that the limits would be established by the regulated industry associations or other groups.

FSIS chose the last alternative. The selected option does not allow retained water in an affected product unless it is an inevitable consequence of the process or processes used to meet applicable food-safety requirements. By ''inevitable consequence,'' the Agency means an unavoidable and irreducible side effect. Under this option, levels of unavoidable retained water must be established by inspected establishments, associations, or other groups, using acceptable protocols. Also, the maximum amount of retained water that can be present must be indicated on the product label. FSIS has found that this option provides more benefits and fewer cost than other options allowing retained water.

Anticipated Cost and Benefits:

In analyzing the impacts of this rule, FSIS has estimated a range of costs the industry will incur. If establishments are able to demonstrate that current levels of retained water are unavoidable in achieving applicable food safety standards, establishments would not incur costs for reducing retained water. These establishments would only incur costs for establishing limits and costs for labeling the product. The costs of establishing limits for the poultry industry are estimated to be $1.5 million. This estimate is based on each establishment's conducting its own tests. The cost should be lower if associations or other groups establish limits for different types of chiller systems. Labeling costs are estimated to be $18.4 million if all raw, single-ingredient poultry continues to retain water.

To the extent that establishments cannot demonstrate that current retained water levels are necessary for achieving applicable food safety standards, significant costs could be incurred as establishments modify processes to minimize retained water levels. Reducing retained water could entail a wide range of processing modifications, depending on the type of chilling equipment currently used and amount of retained water that would have to be removed. FSIS estimates that, if extensive modifications to chilling systems were needed throughout the industry, the fixed costs associated with removing a substantial portion of the existing retained water could run well over $100 million. However, if extensive modifications were not needed, the industry would only incur the costs of establishing retained water limits and meeting the labeling requirements of the final rule. The average retained water for chicken as a percentage of net weight is currently estimated to be in the 5.0 to 6.5 percent range. The corresponding level for turkey is 4.0 to 4.5 percent.

The final rule should not have a significant impact on a large number of small businesses. Fifty to 60 poultry slaughter establishments process under a million birds annually. Many of these smaller operations do not use continuous immersion chillers. They use ice or slush to meet the existing chilling requirements. Few, if any, would have to reduce the current level of retained water. The establishments most affected by this final rule are the firms operating immersion chillers in a manner so as to target the maximum allowable retained water.

The Agency's calculations show the benefits of reducing retained water to be about $72.4 million. Subtracting cost estimates ranging from $18.4 million to $44 million yields expected net benefits of from $28 million to $54 million.

Indirect benefits of this rule could not be quantified. One of the indirect benefits of the rule is the value of consumer information associated with retained water labels. These labels help consumers make informed purchasing decisions and restore consumer sovereignty in retail purchasing.

Another indirect benefit of the rule is the value of reduced cleaning of potential spillage of retained water by consumers. A concomitant effect of reducing spillage is the reduction in bacteria-contaminated water and the associated health hazards to consumers.

An additional indirect benefit is the potential reduction in economic adulteration and misbranding associated with excessive retained water. Finally, the rule will also provide all affected establishments with the flexibility and market incentives to implement new procedures for meeting pathogen reduction performance standards. In addition, by replacing command-and-control requirements with HACCP-consistent performance standards, the final rule will eliminate some recordkeeping and reporting burdens, provide for increased flexibility, and reduce the costs of HACCP implementation.

Risks:

FSIS has identified, as a potential indirect benefit of the rule, reduced spillage of retained water by consumers handling raw products. Reducing the amount of bacteria-contaminated water spilled in consumer households would reduce associated health hazards to consumers. FSIS has not attempted to quantify the reduction of such hazards or any associated foodborne illness.

Timetable:

Action	Date	FR Cite
NPRM	09/11/98	63 FR 48961
NPRM Comment Period End	12/10/98	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

Daniel L. Engeljohn
Director, Regulations Development and Analysis Division
Department of Agriculture
Food Safety and Inspection Service
Washington, DC 20250
Phone: 202 720-5276

RIN: 0583–AC26

USDA—FSIS

18. MEAT PRODUCED BY ADVANCED MEAT/BONE SEPARATION MACHINERY AND RECOVERY SYSTEMS

Priority:

Other Significant

Legal Authority:

21 USC 601 to 695

CFR Citation:

9 CFR 301.2; 9 CFR 318.24 (Revision); 9 CFR 320.1(b)(10)

Legal Deadline:

None

Abstract:

In 1994, the Food Safety and Inspection Service amended its regulations to recognize that product resulting from advanced meat/bone separation machinery comes within the definition of meat when recovery systems are operated to assure that the characteristics and composition of the resulting product are consistent with those of meat. Subsequent compliance problems and other concerns have made it apparent that the regulations are confusing and inadequate to prevent misbranding and economic adulteration. Therefore, FSIS is developing a rule to clarify the regulations and supplement the rules for assuring compliance. The Agency is reviewing information obtained since publication of the proposal.

Statement of Need:

In 1998, FSIS proposed to clarify the meat inspection regulations regarding mechanically separated meat contained in a final rule issued on December 6, 1994. The proposal would replace the compliance program parameters in the 1994 rule with non-compliance criteria for bone solids, bone marrow, and spinal cord tissue. The proposal would require that, as a prerequisite to labeling or using the product derived by mechanically separated skeletal muscle tissue from livestock bones as meat, establishments implement and document procedures for ensuring that their production processes are under control. FSIS expects that the industry would have to modify the manufacturing process it now uses to comply with the proposed criteria and prevent the distribution in commerce of misbranded and economically adulterated meat products.

Summary of Legal Basis:

This action is authorized by the Federal Meat Inspection Act (21 U.S.C. 601 et seq). Exercise of the Secretary of Agriculture's functions under this Act has been delegated to the Under Secretary for Food Safety (7 CFR 2.18) and by the Under Secretary to the Administrator of FSIS (7 CFR 2.53).

Alternatives:

No action.

Anticipated Cost and Benefits:

Although the 1998 proposed rule was considered to be not economically significant, FSIS is restudying the projected costs. The Agency is conducting a new cost-benefit analysis using information from various FSIS data bases and other sources to develop an improved estimate of the costs and benefits and the effect the final rule will have on small entities.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	04/13/98	63 FR 17959
NPRM Comment Period End	06/12/98	
Final Action	10/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

Daniel L. Engeljohn
Director, Regulations Development and Analysis Division
Department of Agriculture
Food Safety and Inspection Service
Washington, DC 20250
Phone: 202 720-5276

RIN: 0583–AC51

USDA—Forest Service (FS)

FINAL RULE STAGE

19. NATIONAL FOREST SYSTEM LAND AND RESOURCE MANAGEMENT PLANNING

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

16 USC 1600 et seq; 5 USC 301

CFR Citation:

36 CFR 219

Legal Deadline:

None

Abstract:

On October 5, 1999, the Forest Service published a proposed rule to guide land and resource management planning for the National Forest System. The proposed planning framework makes sustainability the foundation for National Forest System planning and management and establishes requirements for implementation, monitoring, evaluation, amendment, and revision of land and resource management plans. The intended effects are to simplify, clarify, and otherwise improve the planning process to reduce burdensome and costly procedural requirements and to strengthen collaborative relationships with the public and other government entities. The comment period ended on January 4, 2000.

Statement of Need:

The need for the rule arises from having completed the first round of forest plans as required by the National Forest Management Act. The Forest Service contracted with the Conservation Foundation and Purdue University to conduct a comprehensive critique of the planning process and plan decisions. The critique involved both Agency employees and external participants—State and local governments, businesses, environmental organizations, and others—and resulted in several volumes of findings and recommendations. Key recommendations were to strengthen

the emphasis on ecosystem sustainability and health; to incorporate ecoregional and watershed-level assessments; and to strengthen opportunities for public participation in the planning process and for greater interaction and dialog with Federal, State, local, and Indian tribal governments. Building on those recommendations, the Agency published an advance notice of proposed rulemaking in 1991 and a proposed rule in 1995. During the comment period, a strong concern that the Agency had not chartered a committee of scientists as was required by the statute for the initial planning regulations was identified. In response, the Secretary of Agriculture decided to appoint a committee of scientists to provide advice in the development of a science-based approach to the planning process. The proposed rule was built on the committee's recommendations for achieving more collaborative, dynamic, science-based planning that fosters collaboration among Forest Service officials, State, local, and Indian governments, organizations, and the public at large.

Summary of Legal Basis:

The legal basis for the planned regulatory action is the National Forest Management Act, which requires that regulations be promulgated. This final action will revise the existing regulation which was finalized in 1982.

Alternatives:

Alternatives to this rule that were considered include continuing under existing regulations or staying with the concepts embodied in a 1995 rulemaking effort. The Agency determined that the committee's recommendations should be the basis for a new proposed rule.

Anticipated Cost and Benefits:

A cost-benefit analysis has been completed as part of an Environmental Assessment. Since this regulation governs a process and does not determine an end result, many of the changes from the existing regulation do not lend themselves to a cost-benefit analysis. The cost-benefit analysis identified calculable as well as non-monatized costs and benefits. Based on that analysis, it is anticipated that streamlined planning procedures will result in a reduction in the cost of amending and revising forest plans relative to the same procedures under the existing regulation. In addition, the non-monatized benefits of the rule are expected to be substantial and result in an overall improvement in the public's understanding, use of and benefits from the National Forest System. The rule's emphasis on ecological, economic, and social sustainability collaborative citizen participation and science support of resource decisions provides a framework for increasing public knowledge and understanding of the National Forest System.

Risks:

The planned regulatory action addresses Agency planning procedures and would not directly cause specific risks to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
ANPRM	02/15/91	56 FR 6508
NPRM	04/13/95	60 FR 18886
NPRM Comment Period End	08/17/95	
Second NPRM	10/05/99	64 FR 54074
Comment Period Extended	12/23/99	64 FR 72064
Second NPRM Comment Period End	01/04/00	
Final Action	10/00/00	
Final Action Effective	11/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

Marian P. Connolly
Regulatory Officer
Department of Agriculture
Forest Service
P.O. Box 96090
Washington, DC 20090-6090
Phone: 703 605-4533
Fax: 703 605-5111
Email: mconnolly@fs.fed.us

RIN: 0596–AB20

USDA—FS

20. ADMINISTRATION OF THE FOREST DEVELOPMENT TRANSPORTATION SYSTEM

Priority:

Other Significant

Legal Authority:

16 USC 551; 23 USC 205

CFR Citation:

36 CFR 212

Legal Deadline:

None

Abstract:

This final action consists of adoption of a final rule at 36 CFR part 212 and a final administrative policy to be issued as instruction to Forest Service employees in the Forest Service Manual Title 7700.

It is part of a strategic effort to change how the National Forest road system is improved, maintained, and operated to support the resource objectives of the national forest and grasslands. The intended effect is to shift the focus of the national forest road system from development to restoration and maintenance of those roads needed for recreation, rural access, and the sustainable flow of goods and services, commensurate with the health and productivity of the lands and waters of the National Forest System. An equal objective is to apply science-based analytical tools that will help local forest managers make better informed decisions about road construction, reconstruction, maintenance, and decommissioning. Finally, the rule would redesignate the forest transportation plan as the forest transportation atlas, which would be a repository of important information about the National Forest Transportation System, especially roads.

Key features of the proposed policy include establishing a policy of providing the minimum forest transportation system that will best serve the current and anticipated forest management objectives and public uses, considering both current and likely funding levels. The policy also would adopt the Forest Service report, Roads Analysis Process, Informing Decisions About Managing the National Forest Transportation System 1999, Miscellaneous Report FS-643, as the current standard for a science-based road analysis procedure to help inform decisions about the scope, scale, and need for national forest roads in the context of forest planning, as well as at the site-specific project level. The process will help forest officers set priorities within available funding for construction, reconstruction, maintenance, and decommissioning of roads.

Finally, the proposed policy would establish transitional procedures to ensure more careful consideration when building or reconstructing roads in unroaded portions of inventoried roadless areas and other roadless areas.

These proposed transitional procedures would set a higher standard for road construction in these areas of national forests than in other areas—namely, that any such proposal must meet a compelling need and must be accompanied by an environmental impact statement with the Regional Forester as the responsible official.

Statement of Need:

Few natural resource issues have attracted as much public scrutiny in recent years as the management of the National Forest road system. Few marks on the land are more lasting than those created by road construction. The 380,000 miles of classified National Forest System roads have been funded and constructed primarily through timber harvesting and the development of other resources to provide long-term access for use, management, and protection. In addition, the Agency estimates more than 60,000 miles of unauthorized, unplanned, and temporary roads exist on National Forest System lands. In the last 10 years, public interest in the national forest has shifted substantially toward recreation use and resource protection, while the level of commercial timber sold from the national forests has been reduced significantly.

Consistent with this shift and in light of the backlog of road maintenance needs that are unfunded, and in concert with simultaneous revision of road management administrative direction, this final action will help ensure that additions to the National Forest road system will be those deemed essential for resource management and use; that, to the extent practicable, construction, reconstruction, and maintenance of roads will minimize adverse environmental impact; and finally, that unneeded roads will be decommissioned and, where indicated, ecological processes will be restored.

Alternatives:

Six alternatives were identified through the scoping process and responses to the advance notice of proposed rulemaking, but four of those were considered to be outside the scope or inconsistent with the Agency objectives and were not analyzed in the Environmental Assessment. Only the proposed rule and policy with the transition requirements regarding road construction in roadless areas and a no-action alternative were analyzed in depth.

Anticipated Cost and Benefits:

In most cases, the anticipated costs and benefits associated with the proposed strategy are qualitative, as the proposal provides guidance for transportation planning, but does not dictate land management decisions. Therefore, for the most part, only the expected direction of change can be described. The only exception to this are the potential effects on timber harvest, in which case the maximum potential effects were estimated, assuming for the sake of comparison that no road construction or reconstruction would occur in inventoried roadless and certain unroaded areas.

A qualitative assessment found more factors with expected net positive benefits than expected negative benefits (Table E1 of the cost benefit analysis). The proposed road strategy would clearly result in net benefits through improvements in water quality, wildlife and fish habitat, protection of wilderness areas and passive use values, and reductions of the spread of noxious weeds and invasive plants. More mixed effects are expected for recreation and heritage resources, with likely reductions in some types of roaded access and some improvements or maintenance of more wilderness-type environments. Access for public safety, law enforcement, and access would not be affected. Negative effects are expected from reduced timber harvest and reduced mineral exploration and extraction, particularly during the transition phase.

Risks:

The final rule and policy would not directly cause specific risks to public health, safety, or the environment. However, especially during the interim period in which higher standards apply to any decision authorizing road construction in roadless and unroaded areas, the policy should reduce risks to certain environmental values.

Timetable:

Action	Date	FR Cite
ANPRM	01/28/98	63 FR 4350
ANPRM Comment Period End	03/30/98	
ANPRM Comment Period Extended	03/03/00	65 FR 11676
NPRM	03/03/00	65 FR 11680
NPRM Comment Period End	05/02/00	
Final Action	10/00/00	
Final Action Effective	11/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

Marian P. Connolly
Regulatory Officer
Department of Agriculture
Forest Service
P.O. Box 96090
Washington, DC 20090-6090
Phone: 703 605-4533
Fax: 703 605-5111
Email: mconnolly@fs.fed.us

RIN: 0596–AB67

USDA—FS

21. SPECIAL AREAS: ROADLESS AREA CONSERVATION

Priority:

Other Significant

Legal Authority:

16 USC 472; 16 USC 551; 16 USC 1604; 42 USC 4321

CFR Citation:

36 CFR 294

Legal Deadline:

None

Abstract:

On October 13, 1999, the President directed the Forest Service to begin a public rulemaking process to address roadless areas in the National Forest System. This initiative responded to strong public sentiment for protecting roadless areas and the public benefits those areas provide, including clean water, biological diversity, wildlife habitat, forest health, dispersed recreational opportunities, and other benefits. It also responded to budgetary concerns about the National Forest road system. The public has long questioned the logic of building new roads in roadless areas when the Forest Service receives insufficient funding to maintain its existing road system. The Agency published a notice of intent to prepare an environmental impact statement in the Federal Register on October 19, 1999 (64 FR 56306). The Agency received approximately 365,000 written responses to the notice of intent, including approximately 336,000 form letters, from individuals, groups, organizations, and other government agencies. Following the scoping period in which the Agency held regional public meetings to facilitate public comment on the scope of the environmental analysis and alternatives, the Agency published a

proposed rule in the Federal Register on May 10, 2000 (65 FR 30376). A Draft Environmental Impact Statement was prepared to analyze the preferred and other alternatives. The environmental analysis analyzed (1) the effect of eliminating certain activities, such as road construction in the remaining unroaded portions of inventoried roadless areas on the National Forest System and (2) the effect of establishing criteria and procedures to ensure that the social and ecological values are considered and protected through the forest planning process. The Agency provided copies of the proposed rule, the DEIS, and other relevant information through mailings and the Internet. The comment period ended July 17, 2000. During the comment period, the Agency held over 500 local public meetings to provide information and to receive public comment. The Agency is reviewing the comments and is preparing to publish a final rule in the early winter.

Statement of Need:

Areas that are without roads have inherent values that are increasingly scarce and highly desirable. Under present management policies, the maintenance of areas with these values cannot be guaranteed. At the same time, present and foreseeable funding for road maintenance is expected to be only a small fraction of the total needed to meet environmental and safety standards. Therefore, it is necessary for the Agency to change its policies and practices for roadless area management to reflect different resource priorities and realistic funding levels.

Summary of Legal Basis:

The Forest Service's proposal to initiate a rulemaking process to protect roadless areas comes under applicable administrative and environmental laws, including the Organic Act, the Multiple-Use Sustained-Yield Act, the National Forest Management Act, and the National Environmental Policy Act.

Alternatives:

The Agency could either continue under existing regulations or propose regulations to address the protection of roadless areas.

Anticipated Cost and Benefits:

A cost-benefit analysis has been completed as part of the development of the proposed rule. The benefits of the rule are to preserve the value of areas without roads, including biological diversity, clean water, and other social, economic, and ecological values. Without this protection, the cost to the taxpayer in the future may be considerable, in terms of the loss of desirable aesthetic qualities that are becoming increasingly scarce.

Risks:

The planned regulatory action addresses the protection of roadless areas and would not directly cause specific risks to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
ANPRM	10/19/99	64 FR 56306
ANPRM Comment Period End	12/20/99	
NPRM	05/10/00	65 FR 30288
NPRM Comment Period End	07/17/00	
Final Action	12/00/00	
Final Action Effective	01/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Undetermined

Agency Contact:

Marian P. Connolly
Regulatory Officer
Department of Agriculture
Forest Service
P.O. Box 96090
Washington, DC 20090-6090
Phone: 703 605-4533
Fax: 703 605-5111
Email: mconnolly@fs.fed.us

RIN: 0596–AB77

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DEPARTMENT OF COMMERCE (DOC)

Statement of Regulatory and Deregulatory Priorities

Sustainable, long-term economic growth is a central focus of the President's policies and priorities. The mission of the Department of Commerce (DOC) is to promote job creation and improved standards of living for all Americans through economic growth, technological competitiveness and sustainable development. The Department has strategic goals in three areas related to its mission. They are:

- Expand economic growth, trade, and prosperity;
- Stimulate innovation for American competitiveness; and
- Advance sustainable development.

The Commerce mission statement, containing our three strategic themes, provides the vehicle for understanding Commerce's aims, how they interlock, and how they are to be implemented through our programs. Working collectively, the bureaus of the Department (including the Office of the Secretary) developed this mission statement, with the intent that it serve as both a statement of departmental philosophy and as the guiding force behind the Department's programs.

The importance that this mission statement and these strategic themes have for the Nation is amplified by the vision they pursue for America's communities, businesses, and families. Commerce is one of the smallest Cabinet agencies, yet our presence is felt, and our contributions are found, in every State.

The DOC touches Americans, daily, in many ways—we make possible the weather reports that all of us hear every morning; we facilitate the technology that all of us use in the workplace and in the home each day; we support the development, gathering, and transmitting of information essential to competitive business; we make possible the diversity of companies and goods found in America's (and the world's) marketplace; and we support environmental and economic health for the communities in which Americans live.

The DOC has a clear and powerful vision for itself, for its role in the Federal government, and for its roles supporting the American people, now and in the future. We confront the intersection of trade promotion, civilian technology, economic development, sustainable development, and economic analysis, and we want to provide leadership in these areas for the Nation. As a Department, we aspire to provide programs and services that serve our country's businesses, communities, and families, as initiated and supported by the President and the Congress. We are dedicated to making those programs and services as effective as possible, while ensuring that they are being delivered in the most cost-effective ways. We seek to function in close concert with other agencies having complementary responsibilities so that our collective impact can be most powerful. We seek to meet the needs of our customers quickly and efficiently, with programs, information, and services they require and deserve.

As a permanent part of the Federal Government, but serving an Administration and Congress that can vary with election results, we seek to serve the unchanging needs of the Nation, according to the priorities of the President and the Congress. We are able to do this effectively by functioning in accordance with the legislation that undergirds our programs and by working closely with the President and the committees in Congress, which have programmatic and financial oversight for our programs.

Commerce promotes and expedites American exports, helps nurture business contacts abroad, protects U.S. firms from unfair foreign competition, and makes how-to-export information accessible to small and mid-sized companies throughout the Nation, thereby ensuring that U.S. market opportunities span the globe.

Commerce encourages development in every community, clearing the way for private-sector growth by rebuilding and improving economically deprived and distressed communities. We promote minority entrepreneurship to establish businesses that frequently anchor neighborhoods and create new job opportunities. We work with the private sector to enhance competitive assets.

As the Nation looks to revitalize its industries and communities, Commerce works as a partner with private entities to build America with an eye on the future. Through technology, research and development, and innovation, we are making sure America continues to prosper in the short-term, while also helping industries prepare for long-term success.

Commerce's considerable information capacities help businesses understand clearly where our national and world economies are going, and take advantage of that knowledge by planning the road ahead. Armed with this information, businesses can undertake the new ventures, investments, and expansions that make our economy grow.

The capacity for managing the Nation's assets and resources is another key policy driver for Commerce, an essential one in our ability to help the Nation succeed in the future. These activities—ranging from protecting our fisheries to controlling the radio frequency spectrum to protecting intellectual property—affect the economy directly.

The DOC has instituted programs and policies that lead to cutting-edge, competitive, and better paying jobs. We work every day to boost exports, to deregulate business, to help smaller manufacturers battle foreign competition, to advance the technologies critical to our future prosperity, to invest in our communities, and to fuse economic and environmental goals.

The DOC is American business' surest ally in job creation, serving as a vital resource base, a tireless advocate, and its Cabinet-level voice.

The Department's Regulatory Plan directly tracks these policy and program priorities, only a few of which involve regulation of the private sector by the Department.

Responding to the Administration's Regulatory Philosophy and Principles

The vast majority of the Department's programs and activities do not involve regulation. Of the Department's 12 primary operating units, only five—the Bureau of Export Administration (BXA), the International Trade Administration (ITA), the Economic Development Administration (EDA), the National Oceanic and Atmospheric Administration (NOAA), and the Patent and Trademark Office (PTO)—plan significant preregulatory or regulatory actions for this Regulatory Plan year. Only one of these operating units, NOAA, has a regulatory action rising to the level of the most important of the Department's significant regulatory actions planned for the Regulatory Plan year.

Though not principally a regulatory agency, the DOC has long been a leader in advocating and using market-oriented regulatory approaches in lieu of traditional command-and-control regulations when such approaches offer a better alternative. All regulations are designed and implemented to maximize societal benefits while placing the

smallest possible burden on those being regulated.

The DOC is also refocusing on its regulatory mission by taking into account, among other things, the President's regulatory principles. To the extent permitted by law, all preregulatory and regulatory activities and decisions adhere to the Administration's statement of regulatory philosophy and principles, as set forth in section 1 of Executive Order 12866. Moreover, we have made bold and dramatic changes, never being satisfied with the status quo. Over the past seven years we have emphasized, initiated, and expanded programs that work in partnership with the American people to secure the Nation's economic future. At the same time we have downsized, cut regulations, closed offices, and eliminated programs and jobs that are not part of our core mission. The bottom line is that, after much thought and debate, we have made many hard choices needed to make this Department ''state of the art.''

The Secretary has prohibited the issuance of any regulation that discriminates on the basis of race, religion, gender, or any other suspect category and requires that all regulations be written in simple, plain English and be understandable to those affected by them. The Secretary also requires that the Department afford the public the maximum possible opportunity to participate in departmental rulemakings, even where public participation is not required by law.

Improving the Regulatory Environment for Small Business

The DOC remains committed to its goal of providing small businesses with the least burdensome regulatory environment possible. While we believe small business should remain free from the constraints of regulation whenever possible, the Department realizes that there are times where these entities must be subject to regulation of some kind. But in all cases where small businesses will be affected by DOC regulations, we make every effort to provide them with all relevant and necessary information at the earliest possible time, while making representatives of the Department available to discuss any problems or questions that may arise in complying with these regulations. Additionally, the Department remains committed to providing small businesses with the greatest amount of warning prior to the issuance of any regulation that could affect them directly or indirectly.

Within the Department, the two agencies that regulate activities of small business are the National Oceanic and Atmospheric Administration (NOAA) and the Bureau of Export Administration (BXA). Both NOAA and BXA have taken numerous actions to comply with the Departmental goal of providing small businesses with the least burdensome regulatory environment, while working with small business to ensure that when regulations are issued, small businesses are informed as early as possible and prepared to meet regulatory requirements.

National Oceanic and Atmospheric Administration

When NOAA issues regulations that impact small business, NOAA Special Agents and officers begin an information outreach campaign to educate the regulated community on the new or amended regulations. This outreach campaign involves boarding vessels and visiting fish dealers to explain the new regulations and answer questions regarding compliance. Special Agents and officers educate the regulated community on the technical aspects of the regulations and the conservation value of the management plan and regulations.

It has long been NOAA's practice to answer inquiries by small entities whenever appropriate in the interest of administering statutes and regulations. Inquiries are received via telephone, mail, and electronic mail; during public hearings, town hall meetings, and workshops held by NOAA throughout the year; and in the day-to-day interactions that small entities have with NOAA personnel. As a result, NOAA answers tens of thousands of inquiries from small entities each year.

NOAA also issues written warnings rather than penalties for many minor violations. Since March 1996, NOAA has issued approximately 1,216 written warnings. In addition, NOAA has a ''Summary Settlement System'' that allows violators, including small entities, to choose not to contest an alleged violation and to pay a reduced penalty within a specified time period following receipt of the Summary Settlement Notice. Since March 1996, approximately 708 Summary Settlement offers were extended by NOAA.

NOAA has also established a Fix-It Notice (FIN) program for the reduction or waiver of civil penalties under several of the natural resource protection statutes NOAA enforces, including the Marine Mammal Protection Act, the Endangered Species Act, and the Magnuson-Stevens Fishery Conservation and Management Act. Under the FIN program, dozens of minor, first-time violations that are of a technical nature and do not have a direct natural resource impact, receive a FIN, which allows the violation to be corrected in lieu of a penalty. The FIN identifies the violation and allows the violator a specified amount of time to ''fix'' the violation. At this time, there are over 130 types of violations that have been included in the FIN program. NOAA's Civil Administrative Penalty Schedule has been amended to reflect the FIN program. The FIN program has helped NOAA achieve compliance and has elicited a positive response from the regulated community, which includes small entities.

Bureau of Export Administration

BXA administers a classification and advisory opinion program. Under the Export Administration Regulations (EAR), which set the criteria for export of dual-use items, commercial items with potential military or weapons proliferation applications, an exporter has the responsibility of classifying the item it seeks to export to determine if an export license is required. In light of this responsibility, BXA has established a program whereby an exporter can ask BXA whether the item is subject to the EAR and, if so, the correct classification of that item. Further, for a given end-use, end-user, or destination, BXA will advise an exporter whether an export license is required, or likely to be granted.

BXA has continually used technological advances in order to provide information and customer service to those entities that may be affected by BXA activities. Through its ''Fax-on-Demand'' system, BXA enables exporters to access useful information by facsimile 24-hours a day, and this service has been expanded to provide over 60 documents, including recent regulatory changes, upcoming workshops, useful points of contact, and a wide variety of other competitiveness and trade-related information. BXA also uses its broadcast subscription and broadcast e-mail services, known as ''netFacts,'' combined with its longstanding facsimile service, ''First Facts,'' to provide regular and timely updates regarding regulatory and policy changes and other items of interest to exporters.

In addition, BXA spends a great deal of time educating industry about the export control provisions of the EAR. BXA has an extensive outreach program, conducting seminars throughout the United States and overseas. For example, as a standard part of the seminar, BXA provides a set of guidelines, *Export Management System Guidelines*, to assist firms in ensuring that their exports and export decisions are consistent with the EAR. The EAR also contains ''Know Your Customer'' guidelines and ''red flag'' indicators, designed to assist exporters in complying with regulatory requirements.

The BXA Web site offers those with Internet access to a wide range of export control information, including frequently asked questions, free access to the full text of Export Administration Regulations, and links to other government sites. BXA's Simplified Network Application Process (SNAP) allows submission of license applications and classification requests through the Internet.

Description of Agency Regulations

National Oceanic and Atmospheric Administration

The National Oceanic and Atmospheric Administration (NOAA) establishes and administers Federal policy for the conservation and management of the Nation's oceanic, coastal, and atmospheric resources. It provides a variety of essential environmental services vital to public safety and to the Nation's economy, such as weather forecasts and storm warnings. It is a source of objective information on the state of the environment. NOAA plays the lead role in achieving the departmental goal of promoting stewardship by providing assessments of the global environment.

Recognizing that economic growth must go hand-in-hand with environmental stewardship, the DOC, through NOAA, conducts programs designed to provide a better understanding of the connections between environmental health, economics, and national security. Commerce's emphasis on ''sustainable fisheries'' is saving fisheries and confronting short-term economic dislocation, while boosting long-term economic growth. The Department of Commerce is where business and environmental interests intersect, and the classic debate on the use of natural resources is transformed into a ''win-win'' situation for the environment and the economy.

Three of NOAA's major components, the National Marine Fisheries Service (NMFS), the National Ocean Service (NOS), and the National Environmental Satellite, Data, and Information Service (NESDIS), exercise regulatory authority.

NMFS oversees the management and conservation of the Nation's marine fisheries, protects marine mammals, and promotes economic development of the U.S. fishing industry. NOS assists the coastal states in their management of land and ocean resources in their coastal zones, including estuarine research reserves; manages the Nation's national marine sanctuaries; monitors marine pollution; and directs the national program for deep-seabed minerals and ocean thermal energy. NESDIS administers the civilian weather satellite program and licenses private organizations to operate commercial land-remote sensing satellite systems.

The Administration is committed to an environmental strategy that promotes sustainable economic development and rejects the false choice between environmental goals and economic growth. The intent is to have the Government's economic decisions be guided by a comprehensive understanding of the environment. The DOC, through NOAA, has a unique role in promoting stewardship of the global environment through effective management of the Nation's marine and coastal resources and in monitoring and predicting changes in the Earth's environment, thus linking trade, development, and technology with environmental issues. NOAA has the primary Federal responsibility for providing sound scientific observations, assessments, and forecasts of environmental phenomena on which resource management and other societal decisions can be made.

In the environmental stewardship area, NOAA's goals include: rebuilding U.S. fisheries by refocusing policies and fishery management planning on increased scientific information; increasing the populations of depleted, threatened, or endangered species of marine mammals by implementing recovery plans that provide for their recovery while still allowing for economic and recreational opportunities; promoting healthy coastal ecosystems by ensuring that economic development is managed in ways that maintain biodiversity and long-term productivity for sustained use; and modernizing navigation and positioning services. In the environmental assessment and prediction area, goals include: modernizing the National Weather Service; implementing reliable seasonal and interannual climate forecasts to guide economic planning; providing science-based policy advice on options to deal with very long-term (decadal to centennial) changes in the environment; and advancing and improving short-term warning and forecast services for the entire environment.

Magnuson-Stevens Act Rulemakings

Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) rulemakings concern the conservation and management of fishery resources in the United States 3-to-200-mile Exclusive Economic Zone (EEZ). Among the several hundred rulemakings that NOAA plans to issue in the Regulatory Plan year, a number of the preregulatory and regulatory actions will be significant. The exact number of such rulemakings is unknown, since they are usually initiated by the actions of eight regional Fishery Management Councils (FMCs) that are responsible for preparing fishery management plans (FMPs) and FMP amendments, and for drafting implementing regulations for each managed fishery. Once a rulemaking is triggered by an FMC, the Magnuson-Stevens Act places stringent deadlines upon NMFS by which it must exercise its rulemaking responsibilities. Most of these rulemakings will be minor, involving only the opening or closing of a fishery under an existing FMP. While no one Magnuson-Stevens Act rulemaking is among the Department's most important significant regulatory actions, and, therefore, none is specifically described below, the sum of these actions, and a few of the individual actions themselves, are highly significant.

The Magnuson-Stevens Act, which is the primary legal authority for Federal regulation to conserve and manage fishery resources, establishes eight regional FMCs, responsible for preparing FMPs and FMP amendments. NMFS issues regulations to implement FMPs and FMP amendments. FMPs address a variety of fishery matters, including depressed stocks, overfished stocks, gear conflicts, and foreign fishing. One of the problems that FMPs may address is preventing overcapitalization (preventing excess fishing capacity) of fisheries. This may be resolved by limiting access to those dependent on the fishery in the past and/or by allocating the resource through individual transferable quotas, which can be sold on the open market

to other participants or those wishing access. Quotas set on sound scientific information, whether as a total fishing limit for a species in a fishery or as a share assigned to each vessel participant, enable stressed stocks to rebuild. Other measures include staggering fishing seasons or limiting gear types to avoid gear conflicts on the fishing grounds, and establishing seasonal and area closures to protect fishery stocks.

NMFS favors the concept of framework FMPs where applicable. Such FMPs provide ranges, boundaries, and decision rules within which NMFS can change management measures without formally amending the FMP. Further, consistent with the recommendations on improving regulatory systems, which accompany the Report of the National Performance Review, NMFS favors using market-oriented approaches in managing fisheries. Open-access fisheries are destined to have too many people investing too much money in vessels and equipment. Access controls (e.g., a limited number of permits) represent a rational approach for managing fishery resources; they can be used to control fishing mortality levels and to prevent overfishing, economic dissipation, and subsequent economic and social dislocation. Of course overall quotas will need to be set based on the best scientific information available as to such things as stock status and optimum yields.

The FMCs provide a forum for public debate and, using the best scientific information available, make the judgments needed to determine optimum yield on a fishery-by-fishery basis. Optional management measures are examined and selected in accordance with the national standards set forth in the Magnuson-Stevens Act. This process, including the selection of the preferred management measures, constitutes the development, in simplified form, of an FMP. The FMP, together with draft implementing regulations and supporting documentation, is submitted to NMFS for review against the national standards set forth in the Magnuson-Stevens Act, other provisions of the Act, and other applicable laws. The same process applies to amending an existing approved FMP.

The Magnuson-Stevens Act contains ten national standards against which fishery management measures are judged. NMFS has supplemented the standards with guidelines interpreting each standard, and is currently in the process of updating and adding to those guidelines. One of the national standards requires that management measures, where practicable, minimize costs and avoid unnecessary duplication. Under the guidelines, NMFS will not approve management measures submitted by an FMC unless the fishery is in need of management. Together, the standards and the guidelines correspond to many of the Administration's principles of regulation as set forth in section 1(b) of Executive Order 12866. One of the national standards establishes a qualitative equivalent to the Executive Order's ''net benefits'' requirement—one of the focuses of the Administration's statement of regulatory philosophy as stated in section 1(a) of the Order.

Tortugas Ecological Reserve Regulations, Florida Keys National Marine Sanctuary

Consistent with Executive Order 13089, Coral Reef Protection, which directs the Federal Government to strengthen its stewardship of this Nation's coral reefs and coral reef ecosystems, and the U.S. Coral Reef Task Force's National Action Plan to Conserve Coral Reefs, NOAA has issued a proposed rule to establish the Tortugas Ecological Reserve.

The Tortugas region is located in and just outside the westernmost portion of the Florida Keys National Marine Sanctuary (FKNMS) approximately 70 miles west of Key West, a very strategic position oceanographically that makes it an ideal location for an ecological reserve. It contains the healthiest coral reefs found in the Florida Keys. Coral pinnacles as high as forty feet with the highest coral cover (greater than 30 percent) found in the Keys jut up from the ocean floor. These coral formations are bathed by some of the clearest and cleanest waters found in the Keys. This occurs where the tropical waters of the Caribbean mingle with the more temperate waters of the Gulf of Mexico.

Recent studies reveal that the Tortugas region is unique in its location and the extent to which oceanographic processes impact the area. The Tortugas region plays a dynamic role in supporting marine ecosystems throughout south Florida and the Florida Keys. Larvae that are spawned from adult populations in the Tortugas region are spread throughout the Keys and south and southwest Florida by a persistent system of currents and eddies that provide the retention and current pathways necessary for successful recruitment of both local and foreign spawned juveniles with larval stages remaining from hours for some coral species up to one year for spiny lobster. In addition, the upwellings and convergences of the current systems provide the necessary food supplies in concentrated frontal regions to support larval growth stages.

The intent of the regulations is to expand the existing boundary of the FKNMS by 96 square nautical miles in the remote westernmost portion of the Sanctuary to ensure that sensitive coral habitats lying outside the existing boundary of the Sanctuary are protected and to establish a 151 square nautical mile no-take ecological reserve within that 96 square nautical mile area and within a 55 square nautical mile area of the existing Sanctuary to protect exceptional coral reefs and other habitat, fish, and marine life at the western end of the Florida Keys. The regulations would prohibit consumptive activities, such as fishing and spearfishing, in order to preserve the marine resources of the area. It is anticipated that the creation of the reserve and the related prohibitions will increase the amount of marine life such as lobsters and fish that would be dispersed throughout the Florida Keys.

Despite its beauty and productivity, the Tortugas has been exploited for decades, greatly diminishing its potential as a source of larval recruits to the downstream portion of the Florida Keys and to itself. Fish and lobster populations have been significantly depleted thus threatening the integrity and natural dynamics of the ecosystem. Currently large freighters use Riley's Hump, a significant coral reef structure lying outside the existing Sanctuary boundary as a secure place to anchor between port visits. The several-ton anchors and chains of these ships are devastating large areas of fragile coral reef habitat that provide the foundation for economically important fisheries. By designating this area an ecological reserve, NOAA hopes to create a seascape of promise—a place where the ecosystem's full potential can be realized and a place that humans can learn from and experience.

DOC

FINAL RULE STAGE

22. ● FLORIDA KEYS NATIONAL MARINE SANCTUARY; TORTUGAS ECOLOGICAL RESERVE

Priority:

Other Significant

Legal Authority:

16 USC 1431 et seq

CFR Citation:

15 CFR 922 et seq

Legal Deadline:

None

Abstract:

The final rule will make effective the proposed rule published on May 18, 2000, that would establish a 151 square nautical mile no-take ecological reserve in the Tortugas region of the Florida Keys to protect nationally significant coral reef resources and to protect an area that serves as a source of biodiversity for the Florida Keys National Marine Sanctuary (FKNMS) as well as for the southwest shelf of Florida. The rule would expand the boundary of the FKNMS by 96 square nautical miles in the remote westernmost portion of the FKNMS to ensure that sensitive coral habitats lying outside the existing boundary of the Sanctuary are protected and would establish the reserve within that 96 square nautical mile area and within a 55 square nautical mile area of the existing Sanctuary.

Statement of Need:

This action is consistent with E.O. 13089, Coral Reef Protection, which directs the Federal Government to strengthen its stewardship of this Nation's coral reefs and coral reef ecosystems. Establishment of the Tortugas ecological reserve is consistent with and is one of the key components of the U.S. Coral Reef Task Force's National Action Plan to Conserve Coral Reefs. The Task Force includes the major Federal agencies responsible for the various aspects of coral reef conservation, plus the States and territories.

The Tortugas region is located in and just outside the westernmost portion of the FKNMS approximately 70 miles west of Key West, a very strategic position oceanographically that makes it an ideal location for an ecological reserve. It contains the healthiest coral reefs found in the Florida Keys. Coral pinnacles as high as 40 feet with the highest coral cover (greater than 30%) found in the Keys jut up from the ocean floor. These coral formations are bathed by some of the clearest and cleanest waters found in the Keys. This occurs where the tropical waters of the Caribbean mingle with the more temperate waters of the Gulf of Mexico.

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Despite its beauty and productivity, the Tortugas has been exploited for decades, greatly diminishing its potential as a source of larval recruits to the downstream portion of the Florida Keys and to itself. Fish and lobster populations have been significantly depleted thus threatening the integrity and natural dynamics of the ecosystem. Currently large freighters use Riley's Hump, a significant coral reef structure lying outside the existing Sanctuary boundary as a secure place to anchor between port visits. The several-ton anchors and chains of these ships are devastating large areas of fragile coral reef habitat that provide the foundation for economically important fisheries. By designating this area an ecological reserve, NOAA hopes to create a seascape of promise—a place where the ecosystem's full potential can be realized and a place that humans can learn from and experience.

Summary of Legal Basis:

The National Marine Sanctuaries Act, 16 U.S.C. 1431, et seq., authorizes the Secretary of Commerce to identify and designate areas of the marine environment that are of special national significance as national marine sanctuaries, and to maintain, restore, and enhance living resources by providing places for species that depend upon these marine areas to survive and propagate. The Act authorizes the Secretary to issue such regulations as may be necessary and responsible to implement such designations.

Alternatives:

A no-action and four boundary alternatives for the reserve have been identified. The boundary alternatives vary in size and areas in which they would apply. The smallest would be within the existing FKNMS boundary, would not require a boundary expansion and would consist of approximately 55 square nautical miles. The largest boundary alternative would be approximately 190 square nautical miles in area and would include approximately 135 square nautical miles outside the current FKNMS boundary.

Four regulatory alternatives have been considered, ranging from application of current Sanctuary regulations in the reserve to a proposal that would close part of the reserve to all access and uses except for scientific research and monitoring, and would restrict access to the remainder of the reserve to noncomsumptive activities, with access being controlled by a call-in permit system.

Anticipated Cost and Benefits:

Ecologically, the reserve would provide significant protection of coral reef resources, deepwater fish habitats, and known fish spawning areas.

Socioeconomic impacts, determined by analyzing the costs and benefits of no-take regulations on various industries, indicate moderate impacts on fishermen, mostly lobster and handline fishers, and minimal impacts on recreational fishers. The potential for benefits to nonconsumptive users and the scientific community is high due to the educational and research value of an ecological reserve. Positive effects to surrounding areas through long-term fisheries replenishment are also likely.

Risks:

Despite its beauty and productivity, the Tortugas has been exploited for decades, greatly diminishing its potential as a source of larval recruits to the downstream portion of the Florida Keys and to itself. Fish and lobster populations have been significantly depleted thus threatening the integrity and natural dynamics of the ecosystem. Currently large freighters use Riley's Hump, a significant coral reef structure lying outside the existing Sanctuary boundary as a secure place to anchor between port visits. The several-ton anchors and chains of these ships are devastating large areas of fragile coral reef habitat that provide the foundation for economically important fisheries. By designating this area an ecological reserve, NOAA hopes to create a seascape of promise—a place where the ecosystem's full potential can be realized and a place that humans can learn from and experience.

Timetable:

Action	Date	FR Cite
NPRM	05/18/00	65 FR 31634
Draft EIS	05/19/00	65 FR 31898
Final EIS	10/00/00	
Final Rule	10/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State

Agency Contact:

Billy Causey
Superintendent, Florida Keys National Marine Sanctuary
Department of Commerce
National Oceanic and Atmospheric Administration
P.O. Box 500368
Marathon, FL 33050
Phone: 305 743-2437

RIN: 0648–AO18

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DEPARTMENT OF DEFENSE (DOD)

Statement of Regulatory Priorities

Background

The Department of Defense (DoD) is the largest Federal department consisting of 3 military departments (Army, Navy and Air Force), 9 unified combatant commands, 15 Defense agencies, and 7 DoD field activities. It has over 1,360,000 military personnel and 680,000 civilians assigned as of May 31, 2000, and over 500 military installations and properties in the continental United States, U. S. territories, and foreign countries. The overall size, composition, and dispersion of the Department of Defense, coupled with an innovative regulatory program, presents a challenge to the management of the Defense regulatory efforts under Executive Order 12866 ''Regulatory Planning and Review'' of September 30, 1993.

Because of its diversified nature, DoD is impacted by the regulations issued by regulatory agencies such as the Departments of Energy, Health and Human Services, Housing and Urban Development, Labor, Transportation, and the Environmental Protection Agency. In order to develop the best possible regulations that embody the principles and objectives embedded in Executive Order 12866, there must be coordination of proposed regulations among the regulating agencies and the affected Defense components. Coordinating the proposed regulations in advance throughout an organization as large as DoD is straightforward, yet a formidable undertaking.

DoD is not a regulatory agency but occasionally issues regulations that have an impact on the public. These regulations, while small in number compared to the regulating agencies, can be significant as defined in Executive Order 12866. In addition, some of DoD's regulations may impact the regulatory agencies. DoD, as an integral part of its program, not only receives coordinating actions from the regulating agencies, but coordinates with the agencies that are impacted by its regulations as well.

The regulatory program within DoD fully incorporates the provisions of the President's priorities and objectives under Executive Order 12866. Promulgating and implementing the regulatory program throughout DoD presents a unique challenge to the management of our regulatory efforts.

Coordination

Interagency

DoD annually receives regulatory plans from those agencies that impact the operation of the Department through the issuance of regulations. A system for coordinating the review process is in place, regulations are reviewed, and comments are forwarded to the Office of Management and Budget. The system is working in the Department, and the feedback from the Defense components is most encouraging, since they are able to see and comment on regulations from the other agencies before they are required to comply with them. The coordination process in DoD continues to work as outlined in Executive Order 12866.

Internal

Through regulatory program points of contact in the Department, we have established a system that provides information from the Vice President and the Administrator of the Office of Information and Regulatory Affairs (OIRA) to the personnel responsible for the development and implementation of DoD regulations. Conversely, the system can provide feedback from DoD regulatory personnel to the Administrator, OIRA. DoD continues to refine its internal procedures, and this ongoing effort to improve coordination and communication practices is well received and supported within the Department.

Overall Priorities

The Department of Defense needs to function at a reasonable cost, while ensuring that it does not impose ineffective and unnecessarily burdensome regulations on the public. The rulemaking process should be responsive, efficient, cost-effective, and both fair and perceived as fair. This is being done at a time when there is a significant ongoing downsizing in the Department and it must react to the contradictory pressures of providing more services with fewer resources. The Department of Defense, as a matter of overall priority for its regulatory program, adheres to the general principles set forth in Executive Order 12866 as amplified below.

Problem Identification

Congress typically passes legislation to authorize or require an agency to issue regulations and often is quite specific about the problem identified for correction. Therefore, DoD does not generally initiate regulations as a part of its mission.

Conflicting Regulations

Since DoD plans to issue just one significant regulation this year, the probability of developing conflicting regulations is low. Conversely, DoD is impacted to a great degree by the regulating agencies. From that perspective, DoD is in a position to advise the regulatory agencies of conflicts that appear to exist using the coordination processes that exist in the DoD and other Federal agency regulatory programs. It is a priority in the Department to communicate with other agencies and the affected public to identify and proactively pursue regulatory problems that occur as a result of conflicting regulations both within and outside the Department.

Alternatives

DoD will identify feasible alternatives that will obtain the desired regulatory objectives. Where possible, the Department encourages the use of incentives to include financial, quality of life, and others to achieve the desired regulatory results.

Risk Assessment

Assessing and managing risk is a high priority in the DoD regulatory program. The Department is committed to risk prioritization and an ''anticipatory'' approach to regulatory planning which focuses attention on the identification of future risk. Predicting future regulatory risk is exceedingly difficult due to rapid introduction of new technologies, side effects of Government intervention, and changing societal concerns. These difficulties can be mitigated to a manageable degree through the incorporation of risk prioritization and anticipatory regulatory planning into DoD's decisionmaking process, which results in an improved regulatory process and increases the customer's understanding of risk.

Cost-Effectiveness

One of the highest priority objectives of DoD is to obtain the desired regulatory objective by the most cost-effective method available. This may or may not be through the regulatory process. When a regulation is required, DoD considers incentives for innovation to achieve desired results, consistency in the application of the regulation, predictability of the activity outcome (achieving the expected results), and the costs for regulation development, enforcement, and compliance. These will include costs to the public, Government, and regulated entities, using the best available data or parametric analysis methods, in the

cost-benefit analysis and the decisionmaking process.

Cost-Benefit

Conducting cost-benefit analyses on regulation alternatives is a priority in the Department of Defense so as to ensure that the potential benefits to society outweigh the costs. Evaluations of these alternatives are done quantitatively or qualitatively or both, depending on the nature of the problem being solved and the type of information and data available on the subject. DoD is committed to considering the most important alternative approaches to the problem being solved and providing the reasoning for selecting the proposed regulatory change over the other alternatives.

Information-Based Decisions

The Defense Department uses the latest technology to provide access to the most current technical, scientific, and demographic information in a timely manner through the world-wide communications capabilities that are available on the ''information highway.'' Realizing that increased public participation in the rulemaking process improves the quality and acceptability of regulations, DoD is committed to exploring the use of Information Technology (IT) in rule development and implementation. IT provides the public with easier and more meaningful access to the processing of regulations. Furthermore, the Department endeavors to increase the use of automation in the Notice and Comment rulemaking process in an effort to reduce time pressures in the regulatory process.

Performance-Based Regulations

Where appropriate, DoD is incorporating performance-based standards that allow the regulated parties to achieve the regulatory objective in the most cost-effective manner.

Outreach Initiatives

DoD endeavors to obtain the views of appropriate State, local, and tribal officials and the public in implementing measures to enhance public awareness and participation both in developing and implementing regulatory efforts. Historically, this has included such activities as receiving comments from the public, holding hearings, and conducting focus groups. This reaching out to organizations and individuals that are affected by or involved in a particular regulatory action remains a significant regulatory priority of the Department and, we feel, results in much better regulations.

Coordination

DoD has enthusiastically embraced the coordination process between and among other Federal agencies in the development of new and revised regulations. Annually, DoD receives regulatory plans from key regulatory agencies and has established a systematic approach to providing the plans to the appropriate policy officials within the Department. Feedback from the DoD components indicates that this communication among the Federal agencies is a major step forward in improving regulations and the regulatory process, as well as in improving Government operations.

Minimize Burden

In the regulatory process, there are more complaints concerning burden than anything else. In DoD, much of the burden is in the acquisition area. Over the years, acquisition regulations have grown and become burdensome principally because of legislative action. But, in coordination with Congress, the Office of Federal Procurement Policy, and the public, DoD is initiating significant reforms in acquisition so as to effect major reductions in the regulatory burden on personnel in Government and the private sector. DoD has implemented a multi-year strategy for reducing the paperwork burden imposed on the public. This plan shows that DoD has met and will exceed the goals set forth in the Paperwork Reduction Act. During fiscal year (FY) 2000, the Department achieved a significant reduction in the burden imposed on the public as a result of the review of the information collection requirement in support of the solicitation phase of the Department of Defense acquisition process. The information collection requirement pertains to information that an offeror must submit to DoD in response to DoD solicitations not covered by another Office of Management and Budget (OMB) clearance. DoD reviewed the information being collected under this requirement and reduced the burden hours by 18.4 million hours for an estimated 15 percent reduction during FY 2000.

One significant reduction in burden imposed on the public is planned as a result of the review of the information collection requirement associated with rights in technical data and computer software. We have updated the estimates for the number of respondents and the number of actions to reflect fiscal year 1999 historical data available in the DoD data base. As a result of these reviews, DoD plans to reduce the burden hours imposed on the public under this information collection requirement by an estimated 1.2 million hours per year. It is the goal of the Department of Defense to impose upon the public the smallest burden viable, as infrequently as possible, and for no longer than absolutely necessary.

Plain Language

Ensuring that regulations are simple and easy to understand is a high regulatory priority in the Department of Defense. All too often, the regulations are complicated, difficult to understand, and subject to misinterpretation, all of which can result in the costly process of litigation. The objective in the development of regulations is to write them in clear, concise language that is simple and easy to understand.

DoD recognizes that it has a responsibility for drafting clearly written rules that are reader-oriented and easily understood. Rules will be written for the customer using natural expressions and simple words. Stilted jargon and complex construction will be avoided. Clearly written rules will tell our customers what to do and how to do it. DoD is committed to a more customer-oriented approach and uses plain language rules thereby improving compliance and reducing litigation. One planned initiative that implements the White House memorandum Plain Language in Government Writing, dated June 1, 1998, focuses on DoD's supplement to the Federal Acquisition Regulation (FAR). The goal of this initiative is to clarify the applicability of definitions, eliminate redundant or conflicting definitions, and make definitions easier to find.

In summary, the rulemaking process in DoD should produce a rule that addresses an identifiable problem, implements the law, incorporates the President's policies defined in Executive Order 12866, is in the public interest, is consistent with other rules and policies, is based on the best information available, is rationally justified, is cost-effective, can actually be implemented, is acceptable and enforceable, is easily understood, and stays in effect only as long as is necessary. Moreover, the proposed rule or the elimination of a rule should simply make sense.

Specific Priorities

For this regulatory plan, there are three specific DoD priorities, all of

which reflect the established regulatory principles. One of these, Closed, Transferred, and Transferring Ranges Containing Military Munitions, is a significant regulatory action as defined by E.O. 12866. In those areas where rulemaking or participation in the regulatory process is required, DoD has studied and developed policy and regulation which incorporate not only the provisions of the President's priorities and objectives under the Executive order but also the National Performance Review, dated September 1993.

DoD has focused its regulatory resources on the most serious environmental, health, and safety risks. Perhaps most significant is that each of the three priorities described below promulgates regulations to offset the resource impacts of Federal decisions on the public or to improve the quality of public life, such as those regulations concerning base realignment and closure activities, acquisition, and munitions ranges.

Revitalizing Base Closure Communities – Base Closure Community Assistance (32 CFR Part 175)

Following the July 1993 announcement of the President's program to revitalize base closure communities, Congress created a new property conveyance authority, designed specifically to ease the economic hardship caused by base closures and realignments and to foster rapid job creation in the adversely impacted communities. This authority is referred to as the Economic Development Conveyance (EDC), giving DoD the ability to transfer property to Local Redevelopment Authorities (LRAs) for consideration at or below estimated fair market value to spur economic redevelopment and job creation.

On April 21, 1999, the President and the Secretary of Defense announced their intent to submit legislation that provided for no-cost transfers of EDC property to further stimulate economic redevelopment and long-term job creation and to eliminate delays resulting from prolonged negotiations over fair market value. The initiative also provided for modifying existing EDC agreements, where appropriate, consistent with this new authority. By September 22, 1999, Congress had passed the legislation as part of the National Defense Authorization Act for Fiscal Year 2000, and the President signed it into law on October 5, 1999.

The legislation was designed to directly address the two major hurdles base closure communities currently face, while attempting to effectively reuse closed or realigned bases. First, delays in obtaining control or possession of former base assets delay planning, rehabilitation, modernization, infrastructure improvements, and marketing efforts and, thus, job creation. Second, the costs of basic infrastructure work at a former base necessary to allow these assets to successfully compete for new economic activity is typically extremely high. The no-cost EDC authority provides an opportunity for a collaborative relationship by assisting communities to create jobs on the former installation and relieve DoD of needless caretaker expenses.

To implement this expanded EDC legislative authority, DoD is proceeding to revise DoDI 4165.67 Revitalizing Base Closure Communities–Base Closure Community Assistance, which established policies and procedures for implementing provisions in the National Defense Authorization Act for Fiscal Year 1994 regarding base closure and reuse. Because the March 4, 1996, DoD instruction was published in the **Federal Register** and codified in the Code of Federal Regulations, this revision will be published in the **Federal Register** as an Interim Final Rule.

Reform Defense Acquisition

The Department continues its efforts to reengineer its acquisition system to achieve its vision of an acquisition system that is recognized as being the smartest, most efficient, most responsive buyer of best value goods and services, which meet the warfighter's needs from a globally competitive base. To achieve this vision, the Department will focus in the acquisition regulations arena during this next year on implementing and institutionalizing initiatives that may include additional changes to existing and recently modified regulations to ensure that we are achieving the outcomes we desire (continuous process improvement). The Department will focus on reengineering the process by which it acquires services, focusing on the use of performance-based work statements. The Department also intends to improve its use of electronic commerce/electronic data interchange.

The Department is committed to acquisition reform and continues to make significant improvements in this area, consistent with the National Performance Review and Executive Order 12866. DoD is leading the following initiatives to reform the acquisition process, which include integrating commercial and military facilities and expanding the ability to buy commercial products and expanding the use of commercial procedures.

Integration of commercial and military facilities is critical to enable the Department to capitalize on and access commercial technology and generate funds for modernization, all within a balanced-budget environment. In addition to the need to integrate commercial and military facilities, the Department must expand the use of commercial procedures. Acquisition Reform's Commercial Practices Initiative is geared to providing learning opportunities on key techniques, strategies, and negotiating/pricing tools used in the commercial business environment. Modern, technology-based learning methods and enterprise models of change management are available to meet the needs for both individual and team training. Based on the knowledge gained, the workforce will be enabled to adopt best practices, implement reforms, and understand better how to work with commercial businesses, including ones that are not themselves accustomed to doing business with DoD.

DoD continuously reviews its supplement to the Federal Acquisition Regulation (FAR) and continues to lead Government efforts to simplify the following acquisition processes:

- Rewrite of FAR part 45, Government Property. The goals of the FAR part 45 rewrite are to reduce contractor and Government costs to manage property in the possession of contractors by streamlining recordkeeping requirements; to eliminate requirements to track, report, and inventory property valued at $5,000 or less during contract performance; to replace five inventory schedules with a single inventory disposal schedule; and to shorten screening times prior to disposal. The FAR part 45 rewrite also encourages the dual use of Government property introducing commercial rental practices and reducing property rental rates.
- Review various definitions. The goal of this initiative is to clarify the applicability of definitions, eliminate redundant or conflicting definitions, and make definitions easier to find. This initiative implements the White House memorandum Plain Language in Government Writing, dated June 1, 1998.

- Review of various FAR cost principles. The goal of this initiative is to determine whether certain FAR cost principles are still relevant in today's business environment, whether they place an unnecessary administrative burden on contractors and the Government, and whether they can be streamlined or simplified.
- Review of FAR guidance pertaining to progress payments and other related financing policies. The goal of this initiative is to simplify the progress payments process; to minimize the burdens imposed on contractors and contracting officers; and to expand the use of performance-based payments or commercial financing payments.
- Revise policy on the applicability of cost accounting standards. The goal of this initiative is to modify and streamline the applicability of the Federal cost accounting standards.
- Revise policy on the use of the Governmentwide commercial purchase card. The goal of this initiative is to increase the use of the purchase card for small dollar purchases.
- Revise policy to expand the use of the procedures in FAR part 12, Acquisition of Commercial Items. The goal of this initiative is to expand the use of streamlined procedures for the acquisition of commercial items.
- Revise policy on profit. The goal of this initiative is to make changes to DoD profit policy that would reduce and eventually eliminate emphasis on facilities investment, increase emphasis on performance risk, and encourage contractor cost efficiency.

Closed, Transferred, and Transferring Ranges Containing Military Munitions

The proposed rule, called the Range Rule identifies a process for evaluating appropriate response actions on Closed, Transferred, and Transferring Military Ranges. Response actions will address explosives safety, human health, and the environment. This rule is a process that is consistent with the Comprehensive Environment Response, Compensation, and Liability Act (CERCLA) and tailored to the special risks posed by military munitions and military ranges. This regulation is proposed under the authorities of the Defense Environmental Restoration Program (DERP), 10 U.S.C. 2701 *et seq.*; the DoD Explosive Safety Board (DDESB), 10 U.S.C. 172 *et seq.*; and section 104 of the CERCLA, 42 U.S.C. 9601 *et seq.*, as delegated to the DoD by E.O. 12580 (59 FR 2923 (January 23, 1987)).

The proposed rule was developed with extensive input from the public and other Federal agencies. A draft version of the rule was placed on the World Wide Web; meetings with representatives from State organizations, meetings with public groups, and meetings with other Federal agencies were critical in the formulation of the current draft version of the proposed rule. The public comment period on the rule ended on December 28, 1997, and since that time, DoD has been working with other agencies within the Administration to fully address these comments and to finalize the rule. Currently, a draft final rule is undergoing intra-Administration review as required by E.O. 12866.

DOD

FINAL RULE STAGE

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23. CLOSED, TRANSFERRED, AND TRANSFERRING RANGES CONTAINING MILITARY MUNITIONS

Priority:

Other Significant

Legal Authority:

10 USC 172 et seq; 10 USC 2701 et seq; 42 USC 9601 et seq; EO 12580

CFR Citation:

32 CFR 178

Legal Deadline:

None

Abstract:

The proposal for this Department of Defense (DoD) rule addresses the unique explosives safety considerations associated with military munitions (including UXO) and the need for environmental protection, and it does so under DERP, 10 USC 172 et seq., and CERCLA authorities.

Statement of Need:

The Department of Defense proposed rule identifies a process for evaluating appropriate response actions on closed, transferred, and transferring military ranges. Response actions will address explosives safety, human health, and the environment. The rule is a process consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and is tailored to the special risks posed by military munitions and military ranges.

Summary of Legal Basis:

This regulation is proposed under the authorities of the Defense Environmental Restoration Program (DERP) in 10 USC 2701 et seq.; the DOD Explosive Safety Board (DDESB) in 10 USC 172 et seq.; and section 104 of the CERCLA in 42 USC 9601 et seq., as delegated to the DOD by EO 12580 (59 FR 2923, January 23, 1987).

Alternatives:

A single, specific, and fully integrated process is necessary to avoid confusion and to ensure that effective response activities are undertaken in a fiscally responsible manner. That process must recognize and consider the unique explosives safety hazards associated with military munitions, and concomitantly, with any response activity conducted on closed, transferred, or transferring ranges. The process must ensure that the public and regulators are fully informed and engaged at every stage of the process, including substantial and meaningful public and regulator participation in the response selection and implementation. The process must be accessible and consistent, and lead to informed decisionmaking. DOD considered several alternatives to address military munitions on closed, transferred, or transferring ranges. In doing so, DOD examined the relative merits of conducting responses under any one of the statutorily based processes (DERP, CERCLA, RCRA, 10 USC 172 et seq.) or the status quo in meeting the goal of establishing a single, logical, and comprehensive process that addresses explosives safety, human health, and environmental concerns.

Anticipated Cost and Benefits:

Based on the proposed rule, implementing the proposed rule equates to national incremental costs totaling $709,000,000 over a period of 10 to 15 years with estimated annual costs of $71,000,000 per year for a 10-year period or $47,000,000 per year for a 15-year period. These costs are less than those of other alternatives. Benefits include: Increased protection of the public; increased protection to unexploded ordnance response workers; consistent process; increased public involvement in responses; substantial role for regulatory agencies; and substantial role for other Federal land managers. Implementing a comprehensive approach to respond to these ranges while ensuring public safety, worker safety, and protection of human health and the environment is

essential and would be a beneficial outcome of this rule. Analysis of the anticipated costs and benefits of the draft final rule is ongoing.

Risks:

The degree of risk to the public is lessened by assuring a single, comprehensive process to respond to potential risks to safety, human health, and the environment at all closed, transferred, and transferring ranges. Public and regulatory acceptance of the rule is heightened through pre-proposal dialogue with stakeholders. DoD will continue to work with both public and governmental stakeholders and regulators in developing this proposed rule.

Timetable:

Action	Date	FR Cite
NPRM	09/26/97	62 FR 50796
Public Meetings Begin	10/22/97	
Public Meetings End	12/10/97	
NPRM Comment Period End	12/26/97	62 FR 50796
Final Action	01/00/01	
Final Action Effective	03/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Agency Contact:

Col John Selstrom
Department of Defense
Office of the Secretary
Room 3E787
Deputy Under Secretary of Defense (Environmental Security)
3400 Defense Pentagon
Washington, DC 20301-3400
Phone: 703 697-5372

RIN: 0790–AG46

BILLING CODE 5001–10–S

DEPARTMENT OF EDUCATION (ED)

Statement of Regulatory and Deregulatory Priorities

General

The Department supports States, local communities, and institutions of higher education and others to improve education nationwide. The Department's roles include leadership and financial support for education to agencies, institutions, and individuals in situations where there is a national interest; monitoring and enforcing of civil rights in the area of education; and supporting research, evaluation, and dissemination of findings to improve the quality of education. ED works in partnership with parents, neighborhoods, schools, colleges, educators, business leaders, communities, and States across the country. Since the announcement of President Clinton's ''Regulatory Reinvention Initiative'' on March 4, 1995, the Department has conducted a comprehensive review of its programs, legislation, and implementing regulations to enhance partnerships, increase flexibility, and improve accountability. In response to this initiative, the Department has eliminated or simplified most of its regulations—including the elimination of 2/3 of the regulations applicable to elementary and secondary education programs. The Department has accomplished these results through a departmentwide effort that recognizes that students and educational partners are best served by regulations that focus on critical steps and results, allow as much flexibility as possible consistent with statutory and program goals, and impose the least possible burden.

As part of its regulatory reinvention efforts and in response to the President's memorandum of June 1, 1998, on ''Plain Language in Government Writing,'' the Department also seeks to draft all of its regulations and related documents clearly and concisely in plain language, so that potential program beneficiaries will better understand benefits and requirements. Woven throughout the Department's reinvention is a commitment to provide quality customer service in the spirit of continuous improvement to assure that we are truly ''putting people first.'' The Department listens to our customers to identify their needs and incorporates their suggestions into program goals and strategies.

In order to provide information and support enhanced exchange, the Department instituted 1-800-USA-LEARN (1-800-872-5327) to connect our customers to a ''one-stop-shopping'' center for information about departmental programs and initiatives; 1-800-4FED-AID (1-800-433-3243) for information on student aid; and an on-line library of information on education legislation, research, statistics, and promising programs. Internet address:

http://www.ed.gov.

More than 10,000 people take advantage of these resources every week. The Department has forged effective partnerships with customers and others to develop policies, regulations, guidance, technical assistance, and compliance approaches. The Department has an impressive record of successful communication and shared policy development with affected persons and groups, including parents, representatives of State and local government, institutions of higher education, school administrators, teachers, students, special education and rehabilitation service providers, professional associations, advocacy organizations, business, and labor.

In particular, the Department continues to seek greater and more useful customer participation in its rulemaking activities through the use of consensual rulemaking and new technology. When rulemaking is determined to be absolutely necessary, customer participation is essential and sought at all stages—in advance of formal rulemaking, during rulemaking, and after rulemaking is completed in anticipation of further improvements through statutory or regulatory changes. The Department has expanded its outreach efforts through the use of satellite broadcasts, electronic bulletin boards, and teleconferencing. For example, the Department invites comments on all proposed rules through the Internet.

The Department is streamlining information collections, reducing burden on information providers involved in ED programs, and making information maintained by the Department easily available to the public. Coordinating similar information collections across programs may be one approach to reduce overlapping and inconsistent paperwork requirements. To the extent permitted by statute, regulations will be revised to eliminate barriers that inhibit coordination across programs (such as by creating common definitions), to reduce the frequency of reports, and to eliminate unnecessary data requirements. ED has reduced the information collection burden imposed on the public by 14.7 percent in fiscal year (FY) 1996, by 11 percent in FY 1997, and by more than 5 percent in FY 1998. Our goal for FYs 1999-2000 is a further 10 percent reduction.

The Department's Principles for Regulating, developed in October 1994 during planning to implement the Improving America's Schools Act of 1994, determine when and how it will regulate. Through aggressive application of the following principles, the Department has eliminated outdated or unnecessary regulations and identified situations in which major programs could be implemented without any regulations or with only limited regulations.

Principles for Regulating

The Department will regulate only if regulating improves the quality and equality of services to the Department's customers, learners of all ages. The Department will regulate only when absolutely necessary and then in the most flexible, most equitable, and least burdensome way possible.

Whether to Regulate:

- When essential to promote quality and equality of opportunity in education.
- When a demonstrated problem cannot be resolved without regulation.
- When necessary to provide legally binding interpretation to resolve ambiguity.
- Not if entities or situations to be regulated are so diverse that a uniform approach does more harm than good.

How to regulate:

- Regulate no more than necessary.
- Minimize burden and promote multiple approaches to meeting statutory requirements.
- Encourage federally funded activities to be integrated with State and local reform activities.
- Ensure that benefits justify costs of regulation.
- Establish performance objectives rather than specify compliance behavior.
- Encourage flexibility so institutional forces and incentives achieve desired results.

Regulatory and Deregulatory Priorities for the Next Year

The State Vocational Rehabilitation Services Program

The State Vocational Rehabilitation (VR) Services Program is a $2.5 billion

program that provides funds to State VR agencies to assist individuals with disabilities to achieve employment. These regulations would amend the existing program regulations in 34 CFR part 361 to implement various changes in recently enacted statutes.

ED

FINAL RULE STAGE

24. THE STATE VOCATIONAL REHABILITATION SERVICES PROGRAM (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:

29 USC 711(C)

CFR Citation:

34 CFR 361

Legal Deadline:

None

Abstract:

These regulations are needed to implement changes made by the Rehabilitation Act Amendments of 1998, the Reading Excellence Act, the Carl D. Perkins Vocational and Applied Technology Education Act Amendments of 1998, and the Workforce Investment Act of 1998. This action also results from a review of the existing regulations for this program under section 610 of the Regulatory Flexibility Act (5 U.S.C. 610). The purpose of this review was to determine if these regulations should be continued without change, or should be amended or rescinded, to minimize any significant economic impact upon a substantial number of small entities.

Statement of Need:

These regulations are necessary to implement new legislation. The Department is also completing its review of these regulations under section 610(c) of the Regulatory Flexibility Act. In developing the regulations, the Department will seek to reduce regulatory burden and increase flexibility to the extent possible.

Summary of Legal Basis:

Public Law 105-220, enacted August 7, 1998.

Alternatives:

In addition to implementing the new legislation, the purpose of reviewing these regulations is to determine whether there are appropriate alternatives.

Anticipated Cost and Benefits:

Existing regulatory provisions may be eliminated or improved as a result of this review.

Risks:

These regulations would not address a risk to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	02/28/00	65 FR 10620
NPRM Comment Period End	04/28/00	
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Beverlee Stafford
Director, Planning, Policy, and Evaluation Services
Department of Education
Office of Special Education and Rehabilitative Services
Room 3014
Switzer Building
400 Maryland Avenue SW
Washington, DC 20202-2531
Phone: 202 205-8831

RIN: 1820–AB50

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DEPARTMENT OF ENERGY (DOE)

Statement of Regulatory and Deregulatory Priorities

The Department makes vital contributions to the Nation's welfare through its extraordinary scientific and technical capabilities in energy research, environmental remediation, and national security. The Department's mission is to:

- Enhance the Nation's energy security by developing and deploying clean and affordable energy supplies and by improving the energy efficiency of our economy;
- Maintain the safety, security and reliability of the Nation's nuclear weapons stockpile and reduce the global nuclear danger;
- Clean up former nuclear weapons sites and address the complex challenge of disposing of nuclear wastes; and
- Leverage science and technology to advance fundamental knowledge and our country's competitiveness with stronger partnership with the private sector.

The Department of Energy's regulatory plan reflects the Department's continuing commitment to enhance safety, cut costs, reduce regulatory burden, and increase responsiveness to the public. While not primarily a major Federal regulatory agency, the Department's regulatory activities are essential to achieving its critical mission.

Energy Efficiency Program for Consumer Products and Commercial Equipment

In January 1997, the Department established an Advisory Committee on Appliance Energy Efficiency Standards to assist the Department on issues related to the rulemaking process. The Advisory Committee continues to meet twice a year. During its March 2000 meeting, the Advisory Committee recommended that the Department better inform consumers of the costs and benefits of proposed changes to appliance standards and improve the availability of manufacturer's data on appliance energy efficiency and energy use to the public by making such data accessible electronically. The Department is actively pursuing the first recommendation by adding a summary consumer statement to each consumer rulemaking, which would address the background and rationale for the rulemaking, and address relevant consumer issues. In response to the second recommendation, the Department is attempting, through cooperative efforts with other public and private organizations, to make data on appliance energy efficiency and energy use available to the public over the Internet.

The Department's rulemaking activities, related to energy efficiency standards and determinations, have been categorized as high, medium, or low priority. The schedules in **The Regulatory Plan** and the **Unified Agenda of Federal Regulatory and Deregulatory Actions** reflect priorities established with significant input from the public. The standards rulemakings incorporate the process improvements established in July 1996, which include more workshops to collect public input, and new more transparent forecasting models developed with the help of industry experts, including manufacturers.

The Department made substantial progress during fiscal year 2000 with its high priority standards rulemakings (i.e., clothes washers, fluorescent lamp ballasts, water heaters, and residential central air conditioners and heat pumps). On September 19, 2000, the Department published a final rule for fluorescent lamp ballasts, which was based on a consensus of recommendations from manufacturers and energy conservation advocates. The Department also published a proposed rule for water heaters in April.

During fiscal year 2001, the Department expects to publish final rules establishing energy efficiency standards for clothes washers, residential water heaters, and residential central air conditioners and heat pumps. Additional information and timetables for these actions can be found below.

The Department expects to publish in the coming months proposed rules concerning test procedures for commercial air conditioners and heat pumps, furnaces and boilers, and water heaters. The Department also plans to publish a final rule adopting efficiency standards for certain types of commercial equipment that fall under the scope of the American Society for Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 90.1, and to begin a separate rulemaking for the other equipment under ASHRAE Standard 90.1, where it appears more stringent standards are justified. Information and timetables concerning these actions, other medium and low priority standards rulemakings, and other test procedures can be found in the Department's regulatory agenda, which appears elsewhere in this issue of the **Federal Register**.

Nuclear Safety Regulations

The Department is committed to openness and public participation as it addresses one of its greatest challenges—managing the environment, health, and safety risks posed by its nuclear activities. A key element in the management of these risks is to establish the Department's expectations and requirements relative to nuclear safety and to hold its contractors accountable for safety performance. The 1988 Price-Anderson Amendments Act revisions to the Atomic Energy Act of 1954 (AEA) provide for the imposition of civil and criminal penalties for violations of DOE nuclear safety requirements. As a result, new nuclear safety requirements were initiated with the publication of four notices of proposed rulemaking for review and comment in 1991. The Department's nuclear safety procedural regulations (10 CFR Part 820) were published as a final rule in 1993. Substantive DOE nuclear safety requirements were issued as 10 CFR Parts 830 and 835 (Parts 830 and 835) in 1994 and 1993, respectively. On November 4, 1998, DOE published an amendment to 10 CFR Part 835 to revise Part 835 based on a comprehensive evaluation of the Department's radiation protection program.

In August 1995, the Department published a notice of limited reopening of the comment period to request public comments on the remaining Part 830 and Part 834 rulemakings. The Department has substantially completed the comment resolution process and has addressed the major issues raised by the Defense Nuclear Facilities Safety Board and is engaged in a dialog with the Environmental Protection Agency concerning its comments on Part 834.

The Department recently established an integrated safety management initiative to ensure that safety activities at a DOE site or facility are integrated and appropriate for the work and hazards. One outcome of this initiative, incorporated as part of the contract reform final rule published on June 27, 1997, requires contractors to manage and perform work in accordance with a documented safety management system that ensures that consideration of environment, safety and health issues are integrated into all phases of work. The Department intends to ensure that its nuclear safety regulations are consistent with the integrated safety management process and avoid duplication and counterproductive

efforts. An interim final rule on Part 830 was published on October 10, 2000. The Department expects to issue final rulemakings on Part 830 in December and on Part 834 by April 2001.

Worker Safety Regulations

The Department has a long history of beryllium use because of the element's broad application to many nuclear operations and processes. Beryllium metal and ceramics are used in nuclear weapons, as nuclear reactor moderators or reflectors, and as nuclear reactor fuel element cladding. Inhalation of beryllium dust or particles may cause chronic beryllium disease (CBD) and beryllium sensitization. CBD is a chronic, often debilitating, and sometimes fatal lung condition. Beryllium sensitization is a condition in which a person's immune system becomes highly responsive (allergic) to the presence of beryllium in the body. Based on the number of confirmed cases of CBD and the expected future increase in the number of workers potentially exposed to beryllium during decontamination and decommissioning activities, the Department concluded that there was a compelling need for a chronic beryllium disease prevention program (CBDPP).

In 1996, the Department surveyed its contractors to characterize the extent of beryllium usage, the types of tasks involving beryllium usage, the controls in place for each task, the estimated number of workers exposed during each task, and the estimated exposure levels associated with each task. In addition, the Department established the Beryllium Rule Advisory Committee (BRAC) in June 1997, to advise the DOE on issues pertinent to the proposed rulemaking. The BRAC, which consisted of a diverse set of stakeholders and recognized experts from DOE, other Federal agencies, industry, labor, medicine, and academia, explored issues and generated recommendations for consideration in the development of a chronic beryllium disease prevention rule.

On December 8, 1999, the Department published a final rule in the **Federal Register** (64 FR 68854) establishing the CBDPP, 10 CFR Part 850. This program, which became effective January 7, 2000, will reduce the number of workers at DOE facilities exposed to beryllium, minimize the levels of and potential for exposure to beryllium, and establish medical surveillance requirements to ensure early detection and treatment of disease.

Polygraph Examination Program

Presidential Decision Directive (PDD) 61, *Department of Energy Counterintelligence Program,* dated February 11, 1998, requires DOE to do more to protect the highly sensitive and classified information at its facilities. The President instructed DOE to develop and implement specific measures to reduce the threat to such information, including implementation of a polygraph program.

A counterintelligence-scope polygraph examination both serves as a means to deter unauthorized disclosures of classified information and provides a means for possible early detection of disclosures to enable DOE to take steps promptly to prevent further harm to the national security. Although The Employee Polygraph Protection Act generally prohibits the use of polygraph examinations in private employment settings, it specifically allows for polygraph examinations administered by DOE in the performance of its counterintelligence function to expert, consultant, or contractor employees of DOE in connection with atomic energy defense activities.

As an initial step toward developing and implementing a polygraph examination program, the Department issued an internal directive, DOE Notice 472.2, *Use of Polygraph Examinations,* that establishes a polygraph requirement for Federal employees who occupy or seek to occupy certain sensitive positions at DOE. On December 17, 1999, the Department published a final rule in the **Federal Register** (64 FR 70961) that expanded the polygraph examination program to cover all employees, contractors as well as federal employees, who are in positions with access to the most sensitive categories of classified information and materials. Applicants for such positions were covered as well.

DOE—Energy Efficiency and Renewable Energy (EE)

PROPOSED RULE STAGE

25. ENERGY EFFICIENCY STANDARDS FOR CLOTHES WASHERS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 6295

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Statutory, May 14, 1996.

Abstract:

The Energy Policy and Conservation Act (EPCA), as amended, establishes initial energy efficiency standard levels for most types of major residential appliances and generally requires DOE to undergo two subsequent rulemakings, at specified times, to determine whether the current standard for a covered product should be amended.

This is the second review of the standard for clothes washers.

Statement of Need:

This rulemaking is required by statute. Experience has shown that the choice of residential appliances and commercial equipment being purchased by both builders and building owners is generally based on the initial cost rather than on life-cycle cost. Thus, the law requires minimum energy efficiency standards for appliances to eliminate inefficient appliances and equipment from the market.

Summary of Legal Basis:

The Energy Policy and Conservation Act (EPCA), as amended, establishes initial energy efficiency standard levels for most types of major residential appliances and certain types of commercial equipment and generally requires DOE to undergo rulemakings, at specified times, to determine whether the standard for a covered product should be made more stringent.

Alternatives:

The statute requires DOE to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this

determination, the Department conducts a thorough analysis of alternative standard levels, including the existing standard, based on criteria specified by statute. The process improvements that were recently announced (61 FR 36974, July 15, 1996) further enhance the analysis of alternative standards. For example, DOE will ask stakeholders and private sector technical experts to review its analyses of the likely impacts, costs, and benefits of alternative standard levels. In addition, the Department will solicit and consider information on non-regulatory approaches for encouraging the purchase of energy efficient products.

Anticipated Cost and Benefits:

On May 23, 2000, major stakeholders, including manufacturers and energy efficiency advocates, announced a joint agreement proposing clothes washer efficiency standards to the Department that they both felt were technically feasible and economically justified. The proposed standard would go into effect in two stages. The first stage would begin January 1, 2004, and require that all new residential clothes washers be 22 percent more efficient than today's baseline clothes washer efficiency level. The second stage would begin January 1, 2007, and require that all new residential clothes washers be 35 percent more efficient than today's baseline clothes washer efficiency level. The Department estimates that this proposal would save over 5 quadrillion Btu's of energy over 27 years, while cutting greenhouse gas emissions by an amount equal to that produced by three million cars every year. The water savings would reach up to 11 trillion gallons, enough to supply the needs of 6.6 million households for 25 years.

Risks:

Without appliance efficiency standards, energy use will continue to increase with resulting damage to the environment caused by atmospheric emissions. Enhancing appliance energy efficiency reduces atmospheric emissions of carbon dioxide and nitrogen oxides. Establishing standards that are too stringent could result in excessive increases in the cost of the product, possible reductions in product utility and may place an undue burden on manufacturers that could result in a loss of jobs or other adverse economic impacts.

Timetable:

Action	Date	FR Cite
ANPRM	11/14/94	59 FR 56423
Supplemental ANPRM	11/18/98	63 FR 64343
Workshop	12/15/98	
NPRM	10/05/00	65 FR 59549
NPRM Comment Period End	12/04/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

State, Local

Additional Information:

Due to the Department's limited staff and financial resources, regulatory actions related to energy efficiency standards have been categorized as high, medium, and low priority based on significant input from the public. This action is a high priority, and the Department is working actively on this action.

Agency Contact:

Bryan Berringer, EE-41
Office of Building Research and Standards
Department of Energy
Energy Efficiency and Renewable Energy
1000 Independence Avenue SW.
Washington, DC 20585
Phone: 202 586-0371
Fax: 202 586-4617
Email: bryan.berringer@ee.doe.gov

RIN: 1904–AA67

DOE—EE

26. ENERGY EFFICIENCY STANDARDS FOR CENTRAL AIR CONDITIONERS AND HEAT PUMPS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 6295

CFR Citation:

10 CFR 430.32

Legal Deadline:

Final, Statutory, January 1, 1994.

Abstract:

The Energy Policy and Conservation Act, as amended, establishes initial energy-efficiency standard levels for most types of major residential appliances and generally requires DOE to undergo two subsequent rulemakings, at specified times, to determine whether the extant standard for a covered product should be amended.

This is the initial review of the statutory standards for central air conditioners and heat pumps.

Statement of Need:

This rulemaking is required by statute. Experience has shown that the choice of residential appliances and commercial equipment being purchased by both builders and building owners is generally based on the initial cost rather than on life-cycle cost. Thus, the law requires minimum energy efficiency standards for appliances to eliminate inefficient appliances and equipment from the market.

Summary of Legal Basis:

The Energy Policy and Conservation Act (EPCA), as amended, establishes initial energy efficiency standard levels for most types of major residential appliances and certain types of commercial equipment and generally requires DOE to undergo rulemakings, at specified times, to determine whether the standard for a covered product should be made more stringent.

Alternatives:

The statute requires DOE to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this determination, the Department conducts a thorough analysis of alternative standard levels, including the existing standard, based on criteria specified by statute. The process improvements that were announced (61 FR 36974, July 15, 1996) further enhance the analysis of alternative standards. For example, DOE will ask stakeholders and private sector technical experts to review its analyses of the likely impacts, costs, and benefits of alternative standard levels. In addition, the Department will solicit and consider information on nonregulatory approaches for encouraging the purchase of energy efficient products.

Anticipated Cost and Benefits:

The proposed energy efficiency standards for central air conditioners would provide significant energy savings to the Nation. Over a 25-year

period more than 4 quadrillion Btus of energy would be saved, equivalent to all the energy consumed by nearly 12 million Americans in a single year. These energy savings would also significantly reduce the emissions of air pollutants and greenhouse gases associated with electricity production by avoiding the emission of 60 million tons of carbon and 150 thousand tons of nitrogen oxide. Also, the standards would eliminate the need for the construction of at least 6 new 500-megawatt power plants.

Risks:

Without appliance efficiency standards, energy use will continue to increase with resulting damage to the environment caused by atmospheric emissions. Enhancing appliance energy efficiency reduces atmospheric emissions of carbon dioxide and nitrogen oxides. Establishing standards that are too stringent could result in excessive increases in the cost of the product, possible reductions in product utility and may place an undue burden on manufacturers that could result in a loss of jobs or other adverse economic impacts.

Timetable:

Action	Date	FR Cite
ANPRM	09/08/93	58 FR 47326
Screening Workshop	06/30/98	
Supplemental ANPRM	11/24/99	64 FR 66305
NPRM	10/05/00	65 FR 59589
NPRM Comment Period End	12/04/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local, State

Additional Information:

Due to the Department's limited staff and financial resources, the regulatory actions related to energy efficiency standards have been categorized as high, medium, and low priority based on significant input from the public. This action is a high priority, and the Department is actively working on this action.

Agency Contact:

Michael Raymond, EE-41
Program Manager, Office of Building Research and Standards
Department of Energy
Energy Efficiency and Renewable Energy
1000 Independence Avenue SW.
Washington, DC 20585
Phone: 202 586-9611
Email: michael.raymond@ee.doe.gov

RIN: 1904–AA77

DOE—EE

FINAL RULE STAGE

27. ENERGY EFFICIENCY STANDARDS FOR WATER HEATERS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 6295

CFR Citation:

10 CFR 430.32

Legal Deadline:

Final, Statutory, January 1, 1992.

Abstract:

The Energy Policy and Conservation Act as amended, establishes initial energy-efficiency standard levels for most types of major residential appliances and generally requires DOE to undergo two subsequent rulemakings, at specified times, to determine whether the extant standard for a covered product should be amended.

This is the initial review of the statutory standards for electric water heaters.

Statement of Need:

This rulemaking is required by statute. Experience has shown that the choice of residential appliances and commercial equipment being purchased by both builders and building owners is generally based on the initial cost rather than on life-cycle cost. Thus, the law requires minimum energy efficiency standards for appliances to eliminate inefficient appliances and equipment from the market.

Summary of Legal Basis:

The Energy Policy and Conservation Act (EPCA), as amended, establishes initial energy efficiency standard levels for most types of major residential appliances and certain types of commercial equipment and generally requires DOE to undergo rulemakings, at specified times, to determine whether the standard for a covered product should be made more stringent.

Alternatives:

The statute requires DOE to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this determination, the Department conducts a thorough analysis of alternative standard levels, including the existing standard, based on criteria specified by statute. The process improvements that were recently announced (61 FR 36974, July 15, 1996) further enhance the analysis of alternative standards. For example, DOE will ask stakeholders and private sector technical experts to review its analyses of the likely impacts, costs, and benefits of alternative standard levels. In addition, the Department will solicit and consider information on non-regulatory approaches for encouraging the purchase of energy efficient products.

Anticipated Cost and Benefits:

The Department estimates that the proposed standard will save 4.75 quadrillion Btu's of energy over a 27-year period. The estimated net present value of expected savings is $3.4 billion over the same period. The proposed standard would also produce cumulative greenhouse gas reductions of 83 million metric tons of carbon equilvalent and 229 thousand metric tons of nitrous oxides.

Risks:

Without appliance efficiency standards, energy use will continue to increase with resulting damage to the environment caused by atmospheric emissions. Enhancing appliance energy efficiency reduces atmospheric emissions of carbon dioxide and nitrogen oxides. Establishing standards that are too stringent could result in excessive increases in the cost of the product, possible reductions in product utility and may place an undue burden on manufacturers that could result in a loss of jobs or other adverse economic impacts.

Timetable:

Action	Date	FR Cite
ANPRM	09/28/90	55 FR 39624
NPRM	03/04/94	59 FR 10464
Screening Workshop	06/24/97	
Notice of Availability	01/14/98	63 FR 2186
Impact Workshop	11/09/98	
Workshop	07/23/99	
Reissue NPRM	04/28/00	65 FR 25041
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Local, State

Additional Information:

Due to the Department's limited staff and financial resources, regulatory actions related to energy efficiency standards have been categorized as high, medium, and low priority based on significant input from the public. This action is a high priority, and the Department is working actively on this action.

Agency Contact:

Terry Logee, EE-41
Program Manager, Office of Building Research and Standards
Department of Energy
Energy Efficiency and Renewable Energy
1000 Independence Avenue SW.
Washington, DC 20585
Phone: 202 586-1689
Email: terry.logee@ee.doe.gov

RIN: 1904–AA76

DOE—Departmental and Others (ENDEP)

FINAL RULE STAGE

28. NUCLEAR SAFETY MANAGEMENT

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 2201; 42 USC 7191

CFR Citation:

10 CFR 830

Legal Deadline:

None

Abstract:

This action will add regulations under 10 CFR 830 to establish nuclear safety management requirements for the Department's nuclear facilities. These requirements stem from the Department's obligations to assure adequate protection and to hold contractors who manage and operate these facilities accountable and responsible for safe operations.

Statement of Need:

The purpose of this rule is to ensure that the Department's obligation to protect health and safety is fulfilled and to provide, if needed, a basis for the imposition of civil and criminal penalties consistent with the Price-Anderson Amendments Act of 1988. This action is consistent with the Department's commitment to the issuance of nuclear safety requirements using notice and comment rulemaking.

Summary of Legal Basis:

Under the Atomic Energy Act of 1954, as amended, the Department of Energy has the authority to regulate activities at facilities under its jurisdiction. The Department is committed to honoring its obligation to ensure the health and safety of the public and workers affected by its operations.

Alternatives:

The Department could continue to impose nuclear safety requirements through directives made applicable to DOE contractors through the terms of their contracts.

Anticipated Cost and Benefits:

The incremental costs of the proposed rules should be minimal because contractors are currently bound by comparable contractual obligations. Full compliance by contractors with nuclear safety standards will result in substantial societal benefits.

Risks:

This rulemaking should reduce the risk of nuclear safety problems by clarifying safety requirements applicable to DOE contractors and improving compliance.

Timetable:

Action	Date	FR Cite
NPRM	12/01/91	56 FR 64316
Second NPRM	08/31/95	60 FR 45381
Interim Final Rule	10/10/00	65 FR 60292
Interim Final Rule Comment Period End	11/09/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

Richard L. Black
Director, Office of Nuclear Safety and Policy Standards
Department of Energy
1000 Independence Avenue SW.
Washington, DC 20585
Phone: 301 903-3465

RIN: 1901–AA34

DOE—ENDEP

29. RADIATION PROTECTION OF THE PUBLIC AND THE ENVIRONMENT

Priority:

Other Significant

Legal Authority:

42 USC 2201; 42 USC 7191

CFR Citation:

10 CFR 834

Legal Deadline:

None

Abstract:

This action would add a new 10 CFR 834 to DOE's regulations establishing a body of rules setting forth the basic requirements for ensuring radiation protection of the public and environment in connection with DOE nuclear activities. These requirements stem from the Department's ongoing effort to strengthen the protection of health, safety, and the environment from the nuclear and chemical hazards posed by these DOE activities. Major elements of the proposal included a dose limitation system for protection of the public; requirements for liquid discharges; reporting and monitoring requirements; and residual radioactive material requirements.

Statement of Need:

The purpose of this rule is to ensure that the Department's obligation to protect health and safety is fulfilled and to provide, if needed, a basis for the imposition of civil and criminal penalties consistent with the Price-

Anderson Amendments Act of 1988. This action is consistent with the Department's commitment to the issuance of nuclear safety requirements using notice and comment rulemaking.

Summary of Legal Basis:

Under the Atomic Energy Act of 1954, as amended, the Department of Energy has the authority to regulate activities at facilities under its jurisdiction. The Department is committed to honoring its obligation to ensure the health and safety of the public and workers affected by its operations and the protection of the environs around its facilities.

Alternatives:

The Department could continue to impose nuclear safety requirements through directives made applicable to DOE contractors through the terms of their contracts.

Anticipated Cost and Benefits:

The incremental costs of the proposed rules should be minimal because contractors are currently bound by comparable contractual obligations. Full compliance by contractors with nuclear safety standards will result in substantial societal benefits.

Risks:

This rulemaking should reduce the risk of nuclear safety problems by clarifying safety requirements applicable to DOE contractors and improving compliance.

Timetable:

Action	Date	FR Cite
NPRM	03/25/93	58 FR 16268
Second NPRM	08/31/95	60 FR 45381
Final Action	04/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

Agency Contact:

Andrew Wallo III
Director, Air, Water and Radiation Division
Department of Energy
Office of Environmental Guidance
1000 Independence Avenue SW.
Washington, DC 20585
Phone: 202 586-4996

RIN: 1901–AA38

BILLING CODE 6450–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Statement of Regulatory Priorities

The Department of Health and Human Services (HHS) is the United States Government's principal agency for protecting the health of all Americans and for providing essential human services, especially for those who are least able to help themselves. To carry out its multiple responsibilities, the Department works through ten major operating divisions that manage over 300 programs. This spectrum of activities includes:

- Medicare (health insurance for elderly and disabled Americans);
- Medicaid (health insurance for low-income people);
- Medical and social science research;
- Preventing outbreaks of infectious disease, including immunization services;
- Assuring food and drug safety;
- Financial assistance for low-income families;
- Child support enforcement;
- Improving maternal and infant health;
- Head Start (preschool education and services);
- Preventing child abuse and domestic violence;
- Substance abuse treatment and prevention;
- Services for older Americans, including home-delivered meals; and
- Comprehensive health services delivery for American Indians and Alaskan Natives.

HHS is the largest grant-making agency in the Federal Government, providing some 60,000 grants per year. The Medicare program is the Nation's largest health insurer, handling more than 900 million claims per year. The Department works closely with State and local governments, and many HHS-funded services are provided by State- or local-government agencies, or through private-sector grantees. HHS programs provide for equitable treatment of beneficiaries nationwide, and they enable the collection of national health and other data.

For the foreseeable future, the Department's regulatory priorities, as reflected in the specific Plan entries that follow, involve:

- Protecting the privacy of patients' medical and health insurance records;
- Continuing efforts to strengthen and modernize Medicare, as mandated in recent legislation;
- Several undertakings to assure the safety and efficacy of prescription drugs and medical devices so that consumers may use FDA-regulated products more efficaciously, including new measures reflecting the President's food-safety initiative; and
- New efforts in substance-abuse treatment and prevention.

Underlying the Department's efforts to move forward in these areas in FY 2000 and beyond, there endures the policy framework established by the President's Executive Order 12866, Regulatory Planning and Review. Under the principles set out in this order, the Department assures that its rulemakings: (1) emphasize performance standards and market incentives over prescriptive, command-and-control requirements; (2) reflect the use of cost-benefit and risk assessment analyses to achieve policy objectives in the most efficient manner possible; (3) are developed in consultation with those most affected, especially our partners in the Federal system at the State and local levels; and (4) focus specifically on clearly identified problems, avoiding overly broad, one-size-fits-all approaches to these problems. Efforts to comply with these principles have been a continuing HHS priority since 1993.

The bulk of HHS's regulatory activity emanates from programs of the Food and Drug Administration and the Health Care Financing Administration. The Statement of Regulatory Priorities for these components of the Department follows, below, along with a summary of specific Plan entries.

Food and Drug Administration

The Food and Drug Administration's (FDA) regulatory strategy involves three main goals: (1) to reflect new technologies or programs that will benefit the public, affected industries, and the agency or further protect the public health; (2) to provide more information to consumers so that they may use FDA-regulated products more safely or effectively; and (3) to eliminate unnecessary burdens on industry. The following illustrative examples reflect the agency's efforts to carry out this strategy.

On November 17, 1999, FDA proposed to amend its regulations on nutrition labeling to require that the amount of trans fatty acids present in a food, including dietary supplements, be included in the amount and percent Daily Value (%DV) declared for saturated fatty acids. FDA is proposing that when trans fatty acids are present, the declaration of saturated fatty acids shall bear a symbol that refers to a footnote at the bottom of the nutrition label, which states the number of grams of trans fatty acids present in a serving of the product. FDA also proposed that, wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels, the amount of trans fatty acids be limited as well. This action was also taken to prevent misleading claims and to provide information to assist consumers in maintaining healthy dietary practices.

On December 1, 1999, FDA proposed to revise the status reports section of the postmarketing annual reporting requirements for drug and biological products, and to require applicants to submit annual status reports for certain postmarketing studies of licensed biological products. The proposed rule would describe the types of postmarketing studies covered by these status reports, the information to be included in the reports, and the type of information that FDA would consider appropriate for public disclosure.

On January 26, 2000, FDA amended its regulations governing reporting by manufacturers, importers, distributors and health care (user) facilities of adverse events related to medical devices.

FDA amended its regulations to require that all prescription and over-the-counter (OTC) aqueous-based drug products for oral inhalation be manufactured sterile (May 26, 2000). This rule applies to aqueous-based oral inhalation drug products in both single-dose and multiple-use primary packaging. Pressurized metered-dose inhalers are not subject to this rule. Based on reports of adverse drug experiences from contaminated nonsterile inhalation drug products and recalls of these products, FDA is taking this action to help ensure the safety and effectiveness of these products.

FDA amended its regulations on petitions for the use of food ingredients and sources of radiation (August 25, 2000). The change will permit an efficient, joint review by both FDA and the Food Safety and Inspection Service, U.S. Department of Agriculture, of petitions for approval to use a food ingredient or source of radiation in or on meat or poultry products.

A final rule is in the last stages of completion, which is part of the joint FDA and FSIS farm-to-table food safety system for shell eggs to reduce the risk of foodborne illness. This final rule would establish refrigeration requirements for shell eggs held at retail and labeling requirements instructing egg preparers and consumers on safe

handling of shell eggs. This initiative is in response to the continued reports of outbreaks of foodborne illness and death caused by salmonella enteritidis.

The year 2000 Regulatory Plan entries for FDA include actions as described below.

The agency plans to propose a regulation that would require sponsors of human trials involving human gene therapy or xenotransplantation to submit a redacted version of the original for public disclosure, with an investigational new drug application (IND), an amendment to an IND, or other related documents. Trade secret and personal information would be excluded from the redacted information and made available to the general public.

FDA is proposing to require the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA is taking this action to ensure that it has the appropriate amount of information about bioengineered foods to help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law.

Another initiative would require manufacturers of human cellular and tissue-based products to register with FDA and to submit a list of all products. The final rule is designed to provide a rational, comprehensive, and clear framework for a rapidly growing industry that produces human cellular and tissue based products.

FDA is also placing on the Regulatory Plan a proposed rule that would, as part of implementing the proposed regulatory approach to human cellular and tissue-based products, require manufacturers of human cells and tissue to follow current good tissue practice.

FDA is considering whether to propose to establish regulations that prescribe current good manufacturing practice (CGMP) for dietary supplements and dietary supplement ingredients. CGMP regulations would ensure that consumers are provided with safe dietary supplement products, which meet the quality specifications that the supplements are represented to meet.

A proposed rule would amend the regulations governing the format and content of professional labeling for human prescription drug and biologic products. The proposal would also eliminate certain unnecessary statements that are currently required to appear on prescription drug labels and move certain information to professional labeling.

Another proposed rule would clarify for pharmacies the roles of FDA and the States in regulating pharmacy compounding activities, and define prescription drug compounding activities that fall within FDA's jurisdiction and describe the requirements applicable to those activities. It has been FDA's policy not to interfere with the traditional practice of pharmacy compounding at the retail level. However, changes in the drug delivery system, including the expansion of pharmacy compounding activities, have heightened agency concern for the safety of consumers receiving medications prepared by pharmacy compounding.

A proposed rule would amend the biologics regulations to require that blood establishments prepare and follow written procedures for appropriate action when it is determined that blood and blood components at increased risk for transmitting HCV infection have been collected from a donor who, at a later date, tested repeatedly reactive for evidence of HCV. For a complete listing of the rulemakings associated with the Blood Initiative see the Unified Agenda section. These actions are intended to help ensure the continued safety of the nation's blood supply.

As part of its Food Safety Initiative, FDA and FSIS are committed to developing an action plan to address the presence of salmonella enteritidis in shell eggs and egg products using a farm-to-table approach. FDA will propose to codify egg-relevant provisions of the 1999 Food Code.

Under consideration is a final rule that would establish requirements for a comprehensive food safety assurance program for domestically produced and imported juices based on Hazard Analysis Critical Control Points (HACCP) principles. This initiative is in response to several outbreaks of illness associated with juice products. FDA's current view is that a HACCP system of preventative controls would be an effective and efficient way to ensure that these products are safe.

A proposal would amend the regulation for hearing aids. Current regulations require consumers to be examined by a physician before they purchase a hearing aid, but also allow for a waiver. Because this waiver provision may be misused, FDA is considering whether to eliminate the waiver provision and instead require a medical evaluation when certain previously undiagnosed conditions are found or when the prospective hearing aid user is under 18 years of age. In addition, the agency is considering whether to restrict the dispensing of a hearing aid to patients who have undergone a comprehensive hearing assessment within the past 12 months. This proposal reflects changes in the nature of the causes of hearing loss and the technology of hearing aids. Due to the aging of the population, far fewer cases of hearing loss today are caused by medically treatable conditions, so there may be less need for a medical examination. However, advances in hearing aid technology necessitate proper testing in order for a hearing aid to be effective.

Section 121 of the Food and Drug Administration Modernization Act of 1997 directed FDA to establish requirements for CGMPs for positron emission tomography (PET) drugs, a type of radiopharmaceutical. A proposed rule would adopt CGMPs that reflect the unique characteristics of PET drugs, such as their short half-lives and the fact that they are often, though not always, produced and administered at the same facility. The proposed CGMPs for PET drugs are less detailed and less burdensome than the CGMPs applicable to conventional drugs under 21 CFR parts 210 and 211.

The final document under consideration by FDA is a proposal that would amend the expedited and periodic safety reporting regulations for human drugs and biological products: (1) to revise certain definitions and reporting formats, as recommended by the International Conference on Harmonization, and to define new terms; (2) to add to, or revise current reporting requirements; (3) to revise certain reporting time frames; and (4) to make other revisions to these regulations to enhance the quality of safety reports received by FDA.

Health Care Financing Administration

The Health Care Financing Administration (HCFA) has worked, and continues to work diligently to provide guidance on the many provisions of the Balanced Budget Act legislation. The agency is developing additional appropriate regulations to address provisions that have not yet been implemented in their entirety. HCFA's focus during this coming fiscal year is diverse, encompassing payment issues, program integrity, the children's health insurance program, and managed care.

Payment Regulations

Ambulance Fee Schedule

The Balanced Budget Act of 1997 (BBA) requires the establishment of a fee schedule for ambulance services under the Medicare Program. Policies are being developed through negotiated rulemaking. The negotiated rulemaking committee, representing varied public and private interests related to ambulance services, was scheduled to conclude in February 2000, after taking into account such factors as cost control, geographic and operational differences. Publication of the proposed rule will take place as soon as practical thereafter.

Prospective Payment Systems

Home Health Agencies are currently being paid under an interim payment system in accordance with requirements of the BBA. As also required by the BBA, HCFA is developing a proposed rule to establish requirements for the new Home Health prospective payment system. The same legislation requires a prospective payment system for rehabilitation facilities, now being formulated as a proposed rule. HCFA published a notice of proposed rulemaking on September 8, 1998 for a hospital outpatient prospective payment system, and is drafting a final rule that takes into consideration the comments that we received on the September 1998 document.

Qualifications for Establishing and Maintaining Medicare Billing Privileges

The BBA and other laws require the furnishing of information and the identification of individuals or entities that furnish medical services to beneficiaries before payment can be made. HCFA seeks to ensure that those that provide services to our beneficiaries are qualified to do so. In addition, the agency is responsible for protecting the Trust Funds by ensuring that any duplicate or overpayments are recouped. Through the gathering of information, and the use of unique identifiers for those that furnish services for which Medicare payment may be made, better protection of beneficiaries and public funds can be effected. HCFA is developing a notice of proposed rulemaking to address the use of an information collection instrument that would provide the necessary information before we make a determination of whether a provider or supplier should be granted billing privileges.

Children's Health Insurance Program (CHIP) Regulations

Under this optional program, created as title XXI of the Social Security Act under the BBA, States may initiate and expand child health assistance to uninsured, low-income children. Because of the short timeframe between the enactment of the BBA and the effective date of the legislation, and our interest in ensuring that States could take advantage of the opportunity to better serve their vulnerable youthful populations, HCFA developed guidance that permitted 54 States and territories to have approved CHIP plans. Thus, operation of the CHIP program has begun, prior to the completion of regulations, but pertinent guidance materials will be codified in regulation over the coming year.

Managed Care Regulations

Medicare+Choice

HCFA published an interim final regulation implementing the Medicare+Choice program on June 26, 1998, and a final rule on February 17, 1999, addressing selected issues raised by commenters on the June 1998 regulation. The next final rule under development will be more comprehensive, and it will respond to all comments and implement other changes as necessary.

Medicaid Managed Care

HCFA published a notice of proposed rulemaking on September 29, 1998; addressing the BBA modifications of the Medicaid managed care programs. The publication proposed enhanced enrollee protections and emphasized the quality of health care delivered to Medicaid enrollees. The final rule, under development, will respond to public comments, and make any appropriate revisions necessary to finalize the Medicaid Managed Care programs.

Additional Regulations

HCFA continues to focus on the importance of updating physician payments. A notice of proposed rulemaking was published on July 22, 1999, addressing the updating of physician payments by Medicare, including a provision to change the method of determining malpractice insurance relative value units (RVUs) from the current charge-based system to a resource-based system. The proposal continues the refinement of the practice-expense RVUs that are transitioning from charge-based to resource-based, and it addresses new and revised procedure codes for the year 2000. The final rule, addressing comments received in response to the July 1999 publication, will be published shortly.

HHS—Office of the Secretary (OS)

FINAL RULE STAGE

30. STANDARDS FOR PRIVACY OF INDIVIDUALLY INDENTIFIABLE HEALTH INFORMATION

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal goverments and the private sector.

Legal Authority:

42 USC 1320d-2; 42 USC 1320d-4; PL 104-191, sec 264

CFR Citation:

45 CFR 160; 45 CFR 164

Legal Deadline:

Final, Statutory, February 21, 2000.

Abstract:

The final rule would implement part of the Administrative Simplification requirements of Public Law 104-191 by establishing standards for health plans, health care clearinghouses and certain health care providers to protect the privacy of individually identifiable health information.

Statement of Need:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191) requires the Department to issue final standards for the privacy of individually identifiable health information by February 21, 2000. The confidentiality of such information varies significally. The standards will establish national protections applicable to individually identifiable health information created or maintained by health plans, health clearinghouses, and health providers that conduct transactions electronically.

Summary of Legal Basis:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191) directed the Department to issue several standards to facilitate the electronic exchange of information with respect to financial and administrative transactions. It also

directed the Department to develop and submit to Congress recommendations for privacy legislation. In addition, if Congress did not enact legislation governing privacy standards with respect to individually identifiable health information by August 21, 1999, HIPAA directed the Department to promulgate final regulations containing such standards by February 21, 2000. A proposed rule was published in the fall of 1999. A final regulation reflecting the public comments to the proposal will be issued to satisfy the statutory requirement.

Alternatives:

The Department is required by statute to issue final regulations by February 21, 2000. Therefore, no alternatives to regulatory action have been considered.

Anticipated Cost and Benefits:

The proposal was esimated to cost $3.8 billion. Estimates of the economic impact that will stem from this rule will be revised based on the public comments. A final anaylsis will be included with the final regulation.

Risks:

The extensive comments on the proposed rule provided detailed information on a wide range of important and complex information. The final rule will reflect these insights. Publication of the final rule will enable the Department to meet its statutuary deadline.

Timetable:

Action	Date	FR Cite
NPRM	11/03/99	64 FR 59967
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

State, Local, Tribal, Federal

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Roxanne Gibson
Senior Administrative Assistant
Department of Health and Human Services
Office of the Secretary
Room G-322A, Attention: Privacy-P
200 Independence Avenue SW.
Washington, DC 20201
Phone: 202 260-5083

RIN: 0991–AB08

HHS—Substance Abuse and Mental Health Services Administration (SAMHSA)

FINAL RULE STAGE

31. ● FINAL AND DELEGATION OF AUTHORITY TO IMPLEMENT SAMHSA'S ACCREDITATION BASED SYSTEM FOR OPIOD TREATMENT PROGRAM MONITORING

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

21 USC 823; 42 USC 257a; 42 USC 290aa(d); 42 USC 290dd-2; 42 USC 300x-23; 42 USC 300x-27(a); 42 USC 3007-11

CFR Citation:

42 CFR 8

Legal Deadline:

None

Abstract:

The regulations are divided into three parts. The first establishes the procedures and criteria for becoming an approved accreditation body under the regulations. There are three existing organizations that currently accredit narcotic treatment programs. SAMHSA envisions several authorized accreditation bodies, including some State authorities. This will address the Institute of Medicine (IOM) recommendation to consolidate multiple Federal, State, and local authority inspections.

The second part establishes the criteria and procedures for certification. The Department of Health and Human Services (HHS) certification will form the basis for ''determining the qualifications'' of practitioners under section 303(g) of the Controlled Substances Act, which in turn, will allow DEA to register the program to dispense narcotic drugs. HHS certification will be based primarily upon successful accreditation. This section also sets forth those Federal opiod treatment standards that were identified by the IOM as necessary to prevent substandard treatment. The final rule substantially revises the provisions relating to opiod treatment medications provided for unsupervised use in a manner that will enable stabilized patients to be treated in office-based settings.

The third and final section of the regulations provides a notice and hearing procedure for the Department's suspension or revocation of a treatment program's certification. The procedure is based on the procedure already in place for review of SAMHSA's certification decisions for Federal Workplace Testing Laboratories. This part also provides a procedure for accreditation bodies to use for review of an adverse action taken regarding withdrawal of the accreditation body.

Statement of Need:

The Institute of Medicine completed a study of Federal oversight of methadone clinics. As a direct result of the study, the Food and Drug Administration (FDA) and SAMHSA in collaboration with the National Institute on Drug Abuse, the Drug Enforcement Agency, the Office of National Drug Control Programs, and the Department of Verteran's Affairs, met on several occasions to implement some of the recommendations of that study. Among the recommendations, was a proposal that is implemented, here, which would change the current system for regulating opiod treatment programs from a direct inspection system enforced by the FDA to an accreditation-based system monitored by SAMHSA.

Summary of Legal Basis:

As a narcotic drug intended for the treatment of opiod addiction, methadone is subject to the requirements of the Narcotic Addict Treatment Act (NATA). Under NATA, practitioners who use approved narcotic treatment medications must register separately with the Drug Enforcement Administration (DEA). The DEA registration is based upon the Secretary's determination that the applicant is qualified, under treatment

standards established by the Secretary, to provide such treatment. The Secretary's standards under NATA exist as regulations enforced by the FDA.

Alternatives:

Because FDA's inspection system was established through regulatory action, there is no available alternative to implementing the Institute of Medicine's recommendations regarding an accreditation-based system monitored by SAMHSA without accomplishing the system change through new regulatory action.

Anticipated Cost and Benefits:

The net costs of the new system over the existing FDA system, factoring in SAMHSA's annual oversight costs of $3.4 million, is estimated at an annual $4.4 million level. Additional information on accreditation costs will be derived from SAMHSA's ongoing accreditation project.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	07/22/99	64 FR 39810
Final Rule	02/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Joseph D. Faha
Director, DLEA, SAMHSA
Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Room 12C-15
5600 Fishers Lane
Rockville, MD 20857
Phone: 301 443-4640

RIN: 0930–AA06

HHS—Food and Drug Administration (FDA)

PROPOSED RULE STAGE

32. HEARING AIDS; PROFESSIONAL AND PATIENT LABELING; CONDITIONS FOR SALE

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

This action may affect State, local or tribal goverments and the private sector.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

21 USC 351; 21 USC 352; 21 USC 360d; 21 USC 371; 21 USC 360j(e)

CFR Citation:

21 CFR 801.420; 21 CFR 801.421

Legal Deadline:

None

Abstract:

FDA is considering revising its present regulation governing the labeling and conditions for sale of hearing aids. The present rule requires an examination by a physician before purchase of a hearing aid, but permits an informed adult to waive that requirement. There is some evidence that this waiver provision is being misused.

Statement of Need:

FDA has become aware of changes in the nature of the causes of hearing loss and the technology of hearing aids that necessitate reconsideration of the regulations governing hearing aids. In the past, hearing loss often was caused by medically treatable conditions. Today, medical and/or surgical intervention will correct hearing loss in only 5 to 10 percent of the cases. Therefore, there may be less of a need for medical evaluation. FDA believes, however, that patients should receive proper testing in order for a hearing aid to be effective.

Summary of Legal Basis:

Under 21 U.S.C. 360j(e), FDA has the authority to restrict the sale, distribution, or use of a medical device, if FDA determines that, without such restrictions, there cannot be reasonable assurance of its safety and effectiveness. Under 21 U.S.C. 352, FDA has the authority to require that the labeling of a medical device include adequate directions for use.

Alternatives:

FDA considered applying the rule only to first time purchasers of hearing aids. FDA believes, however, that this would not adequately protect present users of inappropriate or unneeded hearing aids. FDA also considered requiring additional tests, but has preliminarily determined to list these tests as recommended only in order to provide additional flexibility.

Anticipated Cost and Benefits:

FDA is still developing an estimate of the cost of the proposed rule. FDA expects that the benefits from the rule would include: (1) improving the quality of life of hearing aid users; (2) avoiding the cost of inappropriate hearing aid purchase; (3) reducing doctor visits for hearing aid evaluations; (4) lowering treatment costs due to early detection of serious conditions; and (5) encouraging the dissemination of accurate information concerning the benefits and limitations of hearing aids.

Risks:

If the hearing aid purchaser inappropriately waives the medical evaluation requirement under the existing rule, treatable causes of hearing loss may go undetected. Many purchasers who have not had proper testing before a hearing aid purchase will forego the use of a hearing aid because the one purchased does not adequately improve their hearing ability. At this time, FDA believes that many hearing impaired people who may benefit from a hearing aid do not purchase one because they fear that they will not benefit from one due to inaccurate information.

Timetable:

Action	Date	FR Cite
ANPRM	11/10/93	58 FR 59695
ANPRM Comment Period End	01/10/94	
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

Previously reported under RIN 0905-AE46.

Agency Contact:

Joseph M. Sheehan
Chief, Regulations Staff
Department of Health and Human Services
Food and Drug Administration
HFZ-215
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850
Phone: 301 827-2974

RIN: 0910–AA39

HHS—FDA

33. LABELING FOR HUMAN PRESCRIPTION DRUGS; REVISED FORMAT

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

21 USC 321; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

CFR Citation:

21 CFR 201

Legal Deadline:

None

Abstract:

The proposed regulation would amend the regulations governing the format and content of professional labeling for human prescription drug and biologic products, 21 CFR 201.56 and 201.57. The proposal would require that professional labeling include a section containing highlights of prescribing information and a section containing an index to prescribing information, reorder currently required information and make minor changes to its content, and establish minimum graphical requirements for professional labeling. The proposal would also eliminate certain unnecessary statements that are currently required to appear on prescription drug labels and move certain information to professional labeling.

Statement of Need:

The current format and content requirements in sections 201.56 and 201.57 were established to help ensure that labeling includes adequate information to enable health care practitioners to prescribe drugs safely and effectively. However, various developments in recent years, such as technological advances in drug product development, have contributed to an increase in the amount, detail, and complexity of labeling information. This has made it harder for practitioners to find specific information and to discern the most critical information in product labeling.

FDA took numerous steps to evaluate the usefulness of prescription drug labeling for its principal audience and to determine whether, and how, its format and content can be improved. The agency conducted focus groups and a national survey of office-based physicians to ascertain how prescription drug labeling is used by health care practitioners, what labeling information is most important to practitioners, and how professional labeling should be revised to improve its usefulness to prescribing practitioners.

Based on the concerns cited by practitioners in the focus groups and physician survey, FDA developed and tested two prototypes of revised labeling formats designed to facilitate access to important labeling information. Based on this testing, FDA developed a third revised prototype that it made available to the public for comment. Ten written comments were received on the prototype. FDA also presented the revised prototype at an informal public meeting held on October 30, 1995. At the public meeting, the agency also presented the background research and provided a forum for oral feedback from invited panelists and members of the audience. The panelists generally supported the prototype.

The proposed rule attempts to establish format and content requirements for prescription drug labeling that incorporate information and ideas gathered during this process.

Summary of Legal Basis:

The agency has broad authority under sections 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 352, 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262) to regulate the content and format of prescription drug labeling to help ensure that products are safe and effective for their intended uses. A major part of FDA's efforts regarding the safe and effective use of drug products involves FDA's review, approval, and monitoring of drug labeling. Under section 502(f)(1) of the Act, a drug is misbranded unless its labeling bears ''adequate directions for use'' or it is exempted from this requirement by regulation. Under section 201.100 (21 CFR 201.100), a prescription drug is exempted from the requirement in section 502(f)(1) only if, among other things, it contains the information required, in the format specified, by sections 201.56 and 201.57.

Under section 502(a) of the Act, a drug product is misbranded if its labeling is false or misleading in any particular. Under section 505(d) and 505(e) of the Act, FDA must refuse to approve an application and may withdraw the approval of an application if the labeling for the drug is false or misleading in any particular. Section 201(n) of the Act provides that in determining whether the labeling of a drug is misleading, there shall be taken into account not only representations or suggestions made in the labeling, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to the consequences which may result from use of the drug product under the conditions of use prescribed in the labeling or under customary usual conditions of use.

These statutory provisions, combined with section 701(a) of the Act and section 351 of the Public Health Service Act, clearly authorize FDA to promulgate a regulation designed to help ensure that practitioners prescribing drugs (including biological products) will receive information essential to their safe and effective use in a format that makes the information easier to access, read, and use.

Alternatives:

The alternatives to the proposal include not amending the content and format requirements in sections 201.56 and 201.57 at all, or amending them to a lesser extent. The agency has determined that although drug product labeling, as currently designed, is useful to physicians, many find it difficult to locate specific information in labeling, and some of the most frequently consulted and most important information is obscured by other information. In addition, the agency's research showed that physicians strongly support the concept of including a highlights section of the most important prescribing information, an index and numbering system that permits specific information to be easily located, and other proposed requirements, such as the requirement for a minimum type size. Thus, the agency believes that the proposed requirements will greatly facilitate health care practitioners' access and use of prescription drug and biological labeling information.

Anticipated Cost and Benefits:

The expected benefits from the proposed rule include reduced time needed for health care professionals to read or review labeling for desired information, increased effectiveness of treatment, and a decrease in adverse events resulting from avoidable drug-related errors. For example, the proposed revised format is expected to significantly reduce the time spent on reading labeling by highlighting often used information at the beginning of labeling and facilitating access to detailed information.

The potential costs associated with the proposed rule include the cost of redesigning labeling for previously approved products to which the proposed rule would apply and submitting the new labeling to FDA for approval. In addition, one-time and ongoing incremental costs would be associated with printing the longer labeling that would result from additional required sections. These costs would be minimized by applying the amended requirements only to newer products and by staggering the implementation date for previously approved products.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Lee D. Korb
Regulatory Counsel, Regulatory Policy Staff
Department of Health and Human Services
Food and Drug Administration
Suite 3037 (HFD-7)
Center for Drug Evaluation and Research
1451 Rockville Pike
Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

Nancy M. Ostrove
Division of Drug Marketing, Advertising, and Communications
Department of Health and Human Services
Food and Drug Administration
(HFD-42)
Center for Drug Evaluation and Research
5600 Fishers Lane
Rockville, MD 20857
Phone: 301 827-2828

RIN: 0910–AA94

HHS—FDA

34. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262; 42 USC 263; 42 USC 263a-n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b-j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381

CFR Citation:

21 CFR 310; 21 CFR 312; 21 CFR 314; 21 CFR 600; 21 CFR 320; 21 CFR 601; 21 CFR 606

Legal Deadline:

None

Abstract:

The proposed rule would amend the expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonization and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to make other revisions to these regulations to enhance the quality of safety reports received by FDA.

Statement of Need:

FDA currently has safety reporting requirements in section 21 CFR 312.32 for sponsors of investigational drugs for human use. FDA also has safety reporting requirements in sections 21 CFR 310.305, 314.80, 314.90 and 600.80 for applicants, manufacturers, packers and distributors of approved human drug and biological products. FDA has undertaken a major effort to clarify and revise these regulations to improve the management of risks associated with the use of these products. For this purpose, the agency is proposing to implement definitions and reporting formats and standards recommended by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to provide more effective and efficient safety reporting to regulatory authorities worldwide. Currently, the United States, European Union, and Japan require submission of safety information for marketed drug and biological products using different reporting formats and different reporting intervals.

In order to strengthen the agency's ability to monitor the safety of marketed human drug and biological products, FDA is proposing, on its own initiative, certain revisions to its postmarketing safety reporting requirements. For this purpose, the Agency is proposing to require that certain postmarketing safety information that is not currently submitted to FDA in an expedited manner be submitted expeditiously (e.g., domestic reports of medication errors). The Agency is also proposing to revise its existing postmarketing safety reporting regulations to improve the quality of these safety reports (e.g., submission of complete safety information for serious suspected

adverse drug reactions). These changes would enable the Agency to better protect and promote public health.

Summary of Legal Basis:

The agency has broad authority under sections 505 and 701 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262) to monitor the safety of drug and biological products for human use.

Alternatives:

The alternatives to the proposal include not amending our existing safety reporting requirements. This alternative would be inconsistent with FDA's efforts to harmonize its safety reporting requirements with international initiatives and with its mission to protect public health

Anticipated Cost and Benefits:

Manufacturers of human drug and biological products currently have limited incentives to invest capital and resources in standardized global safety reporting systems because individual firms acting alone cannot attain the economic gains of harmonization. This proposed rule would harmonize FDA's safety reporting requirements with certain international initiatives, thereby providing the incentive for manufacturers to modify their safety reporting systems. Initial investments made by manufacturers to comply with the rule are likely to ultimately result in substantial savings to them over time.

The impact on industry includes costs associated with revised safety reporting and recordkeeping requirements. The benefits of the proposed rule are public health benefits and savings to the affected industries. The expected public health benefits would result from the improved timeliness and quality of the safety reports and analyses; making it possible for health care practitioners and consumers to expedite corrective actions and to make more informed decisions about treatments. Savings to the affected industry would accrue from more efficient allocation of resources resulting from international harmonization of the safety reporting requirements.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Agency Contact:

Audrey Thomas
Policy Analyst, Regulatory Policy Staff
Department of Health and Human Services
Food and Drug Administration
Suite 3047 (HFD-7)
Center for Drug Evaluation and Research
1451 Rockville Pike
Rockville, MD 20852
Phone: 301 594-2041

RIN: 0910–AA97

HHS—FDA

35. CURRENT GOOD TISSUE PRACTICE FOR MANUFACTURERS OF HUMAN CELLULAR AND TISSUE-BASED PRODUCTS

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 216; 42 USC 243; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation:

21 CFR 1271

Legal Deadline:

None

Abstract:

As part of implementing the proposed regulatory approach to human cellular and tissue-based products, the Food and Drug Administration (FDA) is proposing to require manufacturers of human cells and tissue to follow current good tissue practice (GTP), which includes proper handling, processing, and storage of human cells and tissue, recordkeeping, and the maintenance of a quality program. FDA is also proposing to amend the current good manufacturing practice regulations that apply to human cellular and tissue-based products, and/or biological products in order to incorporate the new GTP requirements into existing good manufacturing practice regulations.

Statement of Need:

Donor screening and testing, although crucial, are not sufficient to prevent the transmission of disease by human cellular and tissue-based products. Each step in the manufacturing process needs to be controlled. Errors in labeling and testing records, failure to adequately clean work areas, and faulty packaging are examples of improper practices that could lead to a product capable of transmitting disease to a recipient. The agency is concerned about the spread of communicable disease through the use of products whose function and integrity have been impaired. The GTP regulations would govern the method used in, and the facilities and controls used for, the manufacture of human cellular and tissue-based products. GTP requirements are a fundamental component of FDA's risk-based approach to regulating human cellular and tissue-based products.

Summary of Legal Basis:

The Public Health Service Act (42 U.S.C. 216 et seq.) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) authorize FDA to regulate biological products and to ensure that the products are safe, pure, potent, and effective. The Public Health Service Act also contains the authority under which FDA can promulgate regulations designed to prevent the spread of communicable diseases. In order to meet these objectives, FDA must be able to prevent the use of human cellular and tissue-based products whose function and integrity have been impaired by improper and inconsistent manufacturing practices and, which may transmit disease.

Alternatives:

An alternative to the proposed approach would be to continue with the use of industry standards. However, this alternative fails to provide fundamental aspects of product safety. Reliance on industry's voluntary standards for good tissue practice, rather than establishing a regulatory requirement, would not ensure uniform or consistent compliance and would preclude the agency's ability to effectively monitor tissue products to ensure public health and safety.

Anticipated Cost and Benefits:

FDA has estimated that this rule would impose a total annualized cost of $10,613,367 for the entire industry. The primary beneficiaries of the proposed GTP would be the patients who receive the cellular and tissue-based products.

Benefits to patients would result from the reduced risk of communicable disease by avoiding product contamination or product failure through GTP.

Risks:

FDA believes that the risks posed by requiring GTP are minimal. In contrast, failure to reduce the risk of transmission of communicable disease through the use of human cellular and tissue-based products would jeopardize the public health.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Valerie A. Butler
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
Suite 200N (HFM-17)
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448
Phone: 301 827-6210

RIN: 0910–AB28

HHS—FDA

36. PHARMACY AND PHYSICIAN COMPOUNDING OF DRUG PRODUCTS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353a; 21 USC 355; 21 USC 360; 21 USC 371

CFR Citation:

21 CFR 216

Legal Deadline:

None

Abstract:

Section 503A of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353a) describes the circumstances under which compounded drugs may qualify for exemption from three requirements of the Act: (1) that a drug be manufactured according to current good manufacturing practice; (2) that a drug have adequate directions for use; and (3) that a marketing application be approved by FDA before a new drug product is introduced for sale (i.e., sections 501(a)(2)(B), 502(f)(1), and 505 of the Act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355)). To qualify for the exemption, a pharmacist or physician must meet statutory conditions for compounding, including the following: (1) there generally must be a prescription for an identified individual patient before compounding; (2) compounding before receiving a prescription is allowed only under limited circumstances; (3) the quantity of drugs that may be shipped out of state is limited and may vary depending on whether the compounder is located in a state that has entered into a memorandum of understanding (MOU) with FDA; (4) drug products may only be compounded using a bulk drug substance (which is essentially the active ingredient) that is listed in the United States Pharmacopoeia (USP) or National Formulary (NF), or a bulk drug substance that is a component of an FDA-approved drug product, or a bulk drug substance that is listed in the regulation as one that FDA has found to be suitable for compounding; (5) the bulk drug substance must be made in a facility registered with FDA and the bulk drug substance must be accompanied by a certificate of analysis; (6) limited quantities of copies of commercially manufactured drug products may be compounded only in special circumstances; (7) drug products may not be compounded if they are listed in a regulation as having been removed from the market or had their FDA-approval withdrawn because they were found to be not safe or not effective; (8) drug products that are listed in the regulations as ''demonstrably difficult to compound'' may not be compounded. The regulations will amplify and explain the statutory requirements as well as execute tasks Congress assigned FDA in section 503A. This proposed rule will be one of several rulemakings implementing section 503A. Related regulatory initiatives are described below: (1) FDA has issued a final rule listing drug products that may not be compounded because they were found to be not safe or not effective and were removed from the market or had their FDA approval withdrawn; (2) FDA has also issued a proposed rule and is preparing a final rule listing drugs that are not the subject of a USP or NF monograph, and are not components of an FDA-approved drug product but are suitable for compounding; (3) FDA is currently preparing a proposed rule listing those drugs that are demonstrably difficult to compound and are not allowed to be compounded; and (4) FDA has published a Federal Register notice announcing the availability of a draft MOU between FDA and State boards of pharmacy.

Statement of Need:

Pharmacy compounding can provide substantial benefits to the public health. It can give to patients, who are allergic to inactive ingredients found in commercially available drug products, versions of those drug products from which the allergenic ingredient has been omitted. Patients who have difficulty taking a commercially available drug product may obtain a compounded version of the drug product in a different dosage form. In certain instances, pharmacy compounding can also enable physicians to access certain drugs that are not commercially available.

Just as compounded drugs may present significant benefits to health, they can also present significant risks. Compounded drugs are generally not evaluated by FDA for safety or effectiveness. They are not made according to current good manufacturing practices and have generally not been tested for strength, quality, or purity. Stability testing, to establish the useful shelf life of the products, has generally not been performed on compounded drug products. Compounders have made illicit copies of FDA-approved drug products, threatening the integrity of the drug approval process. FDA is attempting to maximize the public health benefits of pharmacy compounding, while minimizing the potential threat to the public health.

Summary of Legal Basis:

Section 127 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) adds section 503A to the Act. Sections 503A(b)(1)(A)(i)(III) and (d)(2) direct FDA to publish regulations establishing a list of drugs that are suitable for compounding. Section 503A(b)(1)(C) directs FDA to publish in the Federal Register a list

of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. Section 503A(b)(1)(D) directs FDA to define the term ''compound regularly or in inordinate amounts'' relating to compounding drug products that are essentially copies of a commercially available drug product. Section 503A(b)(3)(A) directs FDA to develop a list of drug products that may not be compounded because they are demonstrably difficult to compound. Efficient enforcement of section 503A would benefit from publication of a substantive rule that interprets and applies the statutory language.

Alternatives:

Section 127 of FDAMA directs FDA to develop regulations, so no alternatives to regulations have been considered. FDA has considered a wide range of options and approaches within the framework of a regulation. FDA has convened and consulted the Pharmacy Compounding Advisory Committee, which consists of representatives of the United States Pharmacopoeia, the National Association of Boards of Pharmacy, and a consumer organization, as well as members of the pharmacy and pharmaceutical manufacturing industries, physicians and academics.

Anticipated Cost and Benefits:

FDA has not yet quantified the costs and benefits of any regulatory approach. FDA has not been significantly involved in the regulation of pharmacy compounding, and does not have any economic data on the industry at this time. Responses to the NPRM will be important in determining the costs and benefits of any regulation.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	04/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State

Federalism:

Undetermined

Additional Information:

See RINs 0910-AB57, 0910-AB59

Agency Contact:

Wayne H. Mitchell
Regulatory Counsel, Regulatory Policy Staff
Department of Health and Human Services
Food and Drug Administration
Suite 3037 (HFD-7)
Center for Drug Evaluation and Research
1451 Rockville Pike
Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
Email: mitchellw@cder.fda.gov

RIN: 0910–AB58

HHS—FDA

37. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

PL 105-115, sec 121

CFR Citation:

21 CFR 220

Legal Deadline:

Final, Statutory, November 21, 1999.

Abstract:

Positron emission tomography (PET) is a medical imaging modality involving the use of a unique type of radiopharmaceutical drug. PET drugs are usually injected intravenously into patients for diagnostic purposes. Most PET drugs are produced using cyclotrons at locations that are in close proximity to the patients to whom the drugs are administered (e.g., in hospitals or academic institutions). Each PET drug is compounded under a physician's prescription and, due to the short half-lives of PET drugs, is administered to the patient within a few minutes or hours.

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or control used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (CGMP) to assure that the drug meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess. FDA's CGMP requirements for drug products are set forth in 21 CFR parts 210 and 211.

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act (Modernization Act) (Pub. L. 105-115). Section 121 of the Modernization Act contains several provisions affecting the regulation of PET drugs. Section 121(c)(1)(A) of the Modernization Act directs FDA to establish, within two years after enactment, appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(1)(B) requires FDA to consult with patient advocacy groups, professional associations, manufacturers, and other interested persons as the agency develops PET drug CGMP requirements and approval procedures. FDA's proposed rule on PET drug CGMP's will be designed to reflect the unique nature of PET drug products.

Statement of Need:

Congress directed FDA to establish appropriate CGMP requirements for PET drugs. FDA's proposed rule on PET drug CGMP's will be designed to reflect the unique nature of PET drug products. Conformance with these CGMP's should ensure that each PET drug meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess, in accordance with section 501(a)(2)(B) of the Act.

Summary of Legal Basis:

As noted above, section 121(c)(1)(A) of the Modernization Act directs FDA to establish appropriate CGMP requirements for PET drugs. FDA interprets this as a directive to establish regulations on CGMP's for PET drugs because only by adopting regulations can the agency create legally binding requirements.

Alternatives:

FDA has considered several different approaches to establishing CGMP's for PET drugs. In addition, the agency has held public meetings on this matter and has received extensive input from the PET community and other interested persons on what CGMP requirements would be appropriate for PET drugs.

Anticipated Cost and Benefits:

FDA has not yet quantified the costs and benefits of any regulatory approach. The agency has been working with the PET community to develop CGMP's that are appropriately suited to the production of PET drugs while still being consistent with statutory requirements for current good manufacturing practice for drug products. Responses to the proposed rule likely will provide more information on the potential costs and benefits of the proposed CGMP's.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	06/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Wayne H. Mitchell
Regulatory Counsel, Regulatory Policy Staff
Department of Health and Human Services
Food and Drug Administration
Suite 3037 (HFD-7)
Center for Drug Evaluation and Research
1451 Rockville Pike
Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
Email: mitchellw@cder.fda.gov

RIN: 0910–AB63

HHS—FDA

38. CGMPS FOR BLOOD AND BLOOD COMPONENTS: NOTIFICATION OF CONSIGNEES AND TRANSFUSION RECIPIENTS RECEIVING BLOOD AND BLOOD COMPONENTS AT INCREASED RISK OF TRANSMITTING HCV (LOOKBACK)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

21 USC 321; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264; 42 USC 300aa-25; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374

CFR Citation:

21 CFR 606; 21 CFR 610

Legal Deadline:

None

Abstract:

This rulemaking is one of a number of actions being taken to amend the biologics regulations to remove, revise, or update the regulations applicable to blood, blood components, and blood derivatives. These actions are based on a comprehensive review of the regulations performed by FDA, and are also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on House Resources and Intergovernmental Relations, the General Accounting Office, and the Institute of Medicine, as well as public comments. In this rulemaking, FDA will propose to amend the biologics regulations to require that blood establishments prepare and follow written procedures for appropriate action when it is determined that blood and blood components pose an increased risk for transmitting hepatitis C virus (HCV) infection because they have been collected from a donor who, at a later date, tested repeatedly reactive for evidence of HCV.

Statement of Need:

In the Federal Register of October 23, 1998 (63 FR 56198), FDA announced the availability of guidance, which updated previous guidance, providing recommendations for donor screening and further testing for antibodies to HCV, notification of consignees, transfusion recipient tracing and notification, and counseling by physicians regarding transfusion with blood components at increased risk for transmitting HCV (often called ''lookback''). While available evidence indicates that blood establishments are following these recommendations, FDA believes that regulations should be codified, consistent with the previous recommendations, to assure there is clear enforcement authority in case deficiencies in an establishment's lookback program are found and to provide clear instructions for continuing lookback activities.

Summary of Legal Basis:

The Public Health Service Act (21 U.S.C. 216 et seq.) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) authorize FDA to regulate biological products and to ensure that the products are safe, pure, potent, and effective. The Public Health Service Act also contains the authority under which FDA can promulgate regulations to prevent the spread of communicable diseases. These regulations would assure that appropriate action is taken when blood components have been transfused which may potentially be capable of transmitting HCV, that persons who have been transfused with such blood components are notified so that they receive proper counseling and treatment, and to help prevent the further transmission of HCV.

Alternatives:

FDA has considered permitting the continued voluntary compliance with the recommendations that have already issued. However, the ability of FDA to enforce appropriate lookback procedures would be unclear. In addition, because lookback will remain appropriate for the foreseeable future, FDA believes that the procedures should be clearly established in the regulations.

Anticipated Cost and Benefits:

FDA is in the process of analyzing the costs related to the rulemaking. Monetary burdens will be associated to the tracing of previous donations of donors, identifying the recipients of these previous blood donations, and notifying these recipients, as appropriate. FDA believes these costs will be more than compensated by the public health benefits, including benefits related to the notification of past transfusion recipients who may be unaware that they may be infected with HCV.

Risks:

FDA believes there are minimum risks posed by requiring that appropriate lookback procedures for HCV be prepared and followed.

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

See RIN 0910-AB26.

Agency Contact:

Steven F. Falter
Director, Regulations and Policy Staff
Department of Health and Human Services
Food and Drug Administration
Suite 200N (HFM-17)
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448
Phone: 301 827-6210
Fax: 301 594-1944
Email: falter@cber.fda.gov

RIN: 0910–AB76

HHS—FDA

39. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY SUPPLEMENTS

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

21 USC 342; 21 USC 371; 21 USC 374; 42 USC 264

CFR Citation:

21 CFR 111

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) announced in an advance notice of proposed rulemaking (ANPRM) of February 6, 1997 (62 FR 5700), its plans to consider developing regulations establishing current good manufacturing practices (CGMP) for dietary supplements and dietary ingredients. The ANPRM was published in order for FDA to solicit comments on whether it should initiate action to establish CGMP regulations and if so, what constitutes CGMP for these products. FDA announced that this effort was in response to the section of the Federal Food, Drug, and Cosmetic Act (the Act) that provides authority to the Secretary of Health and Human Services to promulgate CGMP regulations and to a submission from the dietary supplement industry asking that FDA consider an industry-proposed CGMP framework as a basis for CGMP regulations. The ANPRM also responds to concerns that such regulations are necessary to ensure that consumers are provided with dietary supplement products which have not been adulterated as a result of manufacturing, packing, or holding; which have the identity and provide the quantity of dietary ingredients declared in labeling; and which meet the quality specifications that the supplements are represented to meet.

Statement of Need:

FDA intends to publish a proposed rule to establish current good manufacturing practices (CGMP) for dietary supplements and dietary ingredients for several reasons. First, FDA is concerned that some firms may not be taking appropriate steps during the manufacture of dietary supplements and dietary ingredients to ensure that products are not adulterated as a result of manufacturing, packing, or holding. There have been cases of misidentified ingredients harming consumers using dietary supplements. FDA is also aware of products that contain potentially harmful contaminants because of apparently inadequate manufacturing controls and quality control procedures. The agency believes that a system of CGMP is the most effective and efficient way to ensure that these products will not be adulterated during manufacturing, packing, or holding.

Summary of Legal Basis:

If CGMP regulations were adopted by FDA, failure to manufacture, pack, or hold dietary supplements or dietary ingredients under CGMP regulations would render the dietary supplement or dietary ingredients adulterated under section 402(g) of the Act.

Alternatives:

The two principal alternatives to comprehensive CGMP are end-product testing and Hazard Analysis Critical Control Points (HACCP). In the ANPRM, FDA asked for public comment on approaches to ensure that dietary supplements and dietary ingredients are not adulterated during the manufacturing process. The agency asked whether HACCP may be a more effective approach than a comprehensive CGMP, and whether different approaches may be better able to address the needs of the broad spectrum of firms that conduct one or more distinct operations, such as the manufacture of finished products, or solely the distribution and sale of finished products at the wholesale or retail level. FDA will consider the information it received in response to the ANPRM and from other sources, such as public meetings and small business outreach meetings, in its consideration of whether CGMP or other approaches are most appropriate.

Anticipated Cost and Benefits:

A comprehensive CGMP (or other system of ensuring that dietary supplements and dietary ingredients are not adulterated during manufacturing, packing, or holding) would permit more effective and efficient oversight by Federal, State, and local governments. It would place primary responsibility for ensuring that these products are not adulterated during manufacturing, packing, or holding on the manufacturer, packer or holder by requiring that they implement a system to control their processes. FDA anticipates that costs to industry generated by implementing a comprehensive manufacturing process, whether CGMP or other plan, would be offset in four ways: (1) by reducing the amount of supplement-associated illnesses or adverse events; (2) by increasing public confidence in dietary supplements marketed in the United States; (3) by enabling U.S. supplements companies to compete more effectively in the world market; and (4) by decreasing the number of future product recalls.

Risks:

Any potential for consumers to be provided adulterated (contaminated with industrial chemicals, pesticides, microbial pathogens, or dangerous misidentified ingredients or toxic components of ingredients) products must be considered a very serious risk because of the possibility that such contamination could be widespread, affecting whole segments of the population, causing some severe long-term effects and even loss of life. Dietary supplements are used by a large segment of the American public. Moreover they are often used by segments of the population that are particularly vulnerable to adulterated products, such as the elderly, young children, pregnant and nursing women, and persons who may have serious illnesses or are taking medications that may adversely interact with dietary supplements. FDA has adopted or proposed manufacturing controls for a number of foods and commodities that present potential health hazards to consumers if not processed properly, including seafood, juice products, and fruits and vegetables and it is appropriate that FDA consider whether manufacturing controls are necessary to assure consumers that dietary supplements are not adulterated during the manufacturing, packing, or holding process.

Timetable:

Action	Date	FR Cite
ANPRM	02/06/97	62 FR 5700
ANPRM Comment Period End	06/06/97	
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Karen Strauss
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
(HFS-820)
200 C Street SW
Washington, DC 20204
Phone: 202 205-5372
Fax: 202 260-8957
Email: kfs@cfsan.fda.gov

RIN: 0910–AB88

HHS—FDA

40. AVAILABILITY FOR PUBLIC DISCLOSURE AND SUBMISSION TO FDA FOR PUBLIC DISCLOSURE OF CERTAIN DATA AND INFORMATION RELATED TO GENE THERAPY OR XENOTRANSPLANTATION

Priority:

Other Significant

Legal Authority:

5 USC 552; 21 USC 331(j); 21 USC 355

CFR Citation:

21 CFR 20.100; 21 CFR 312.42; 21 CFR 312.130; 21 CFR 601.50; 21 CFR 601.51; 21 CFR 601.52; 21 CFR 601.53

Legal Deadline:

None

Abstract:

The proposed regulation would require sponsors of human trials involving human gene therapy or xenotransplantation to submit a redacted version of the original for public disclosure, with an investigational New Drug Application (IND), an amendment to an IND, or other related documents. The submission would be redacted to exclude trade secret information and personal information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. FDA would then make the redacted documents available to the general public and the information may be discussed in open session at scientific advisory committee meetings and at other suitable fora.

Statement of Need:

Information concerning investigational new drugs, including those biological drugs related to human gene therapy and xenotransplantation, are generally held as confidential by the Food and Drug Administration pending completion of the clinical studies and approval of the new drug. For clinical studies, involving either human gene therapy or xenotransplantation, there are multiple complex and controversial issues that must be fully discussed by scientists and the general public. These issues include both safety concerns and ethical questions, which must be fully discussed, understood, and resolved on an international level before these promising therapies may be fully studied and implemented. FDA is issuing this proposed rule to assure that information that is necessary for these discussions are available to the public.

Summary of Legal Basis:

Under the Freedom of Information Act (FOIA), 5 U.S.C. 552, Federal agencies must, with certain exceptions, disclose information in their files to the public on request. One exemption protects trade secrets and confidential commercial information from public disclosure. (See 5 U.S.C. 552(b)(4)). The information that may be made publicly available as a result of this rulemaking includes information currently made public by Federal agencies other than FDA, at Federal advisory committee meetings or other public workshops, and through general commercial disclosure. Thus, this information is no longer considered to be ''confidential commercial information.'' Trade secrets would continue to be protected under the regulations. In addition, under FDA's broad rulemaking authority (21 U.S.C. 201, et seq.), and under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)), FDA has the authority to issue regulations imposing conditions on the investigation of new drugs as necessary ''relating to the public health.'' Because of the public health issues related to these therapies, and the necessity that these issues be fully aired and the public fully informed, these regulations are intended to promote the public health.

Alternatives:

FDA considered providing for the voluntary disclosure of this information by study sponsors, without a regulatory requirement to do so. This alternative would not be less burdensome, unless an establishment failed to voluntarily disclose, and the agency would have no means of assuring the quality, consistency, and timeliness of the information disclosed.

FDA also considered assuming the responsibility for redaction of documents already being submitted by study sponsors and providing the redacted information to the public. Although this alternative would reduce direct costs to the sponsors, FDA has limited resources to perform this task, resulting in delays in providing the public this important information and possibly causing delays in research.

Anticipated Cost and Benefits:

FDA has estimated that this rule would cost a total of approximately $120,000 per year for a total of approximately 150 sponsors (approximately $800 per sponsor). The proposed rule would provide an improved means of managing public health risks, including by informing potential study subjects of potential risks and by assuring that public health and ethical issues are fully considered by those concerned with the public health.

Risks:

There is a risk that the information that would be disclosed may be misinterpreted or misunderstood by some in the public. However, by providing for complete disclosure of relevant information, FDA believes that such misunderstandings are less likely to occur than under current practice where complete information may not be made available.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Steven F. Falter
Director, Regulations and Policy Staff
Department of Health and Human Services
Food and Drug Administration
Suite 200N (HFM-17)
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448
Phone: 301 827-6210
Fax: 301 594-1944
Email: falter@cber.fda.gov

RIN: 0910–AC00

HHS—FDA

41. ● CONTROL OF SALMONELLA ENTERITIDIS IN SHELL EGGS DURING PRODUCTION AND RETAIL

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

21 USC 342(a)(4); 21 USC 371(a); 42 USC 264

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

The President's Council on Food Safety was established in August 1998 to improve the safety of the food supply through science-based regulations and well-coordinated inspection, enforcement, research, and education programs. The Council has identified egg safety as one component of the public health issue of food safety that warrants immediate Federal, interagency action.

In July 1999, FDA and FSIS committed to developing an action plan to address the presence of salmonella enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items for the action plan. The Egg Safety Action Plan was announced by the President on December 11, 1999. The goal of the Action Plan is to reduce egg-related SE illnesses by 50 percent by 2005 and eliminate egg-related SE illnesses by 2010.

The Egg Safety Action Plan consists of eight objectives covering all stages of the farm-to-table continuum as well as support functions. On March 30, 2000 (Columbus, OH), and April 6, 2000 (Sacramento, CA), joint public meetings were held by FDA and FSIS to solicit and discuss information related to the implementation of the objectives in the Egg Safety Action Plan.

In accordance with discussions at the public meetings, FDA intends to publish a proposed rule to require that shell eggs be produced under an SE risk reduction plan that is designed to prevent transovarian SE from contaminating eggs at the farm during production.

Because egg safety is a farm-to-table effort, FDA intends to include in its proposal certain provisions of the 1999 Food Code that are relevant to how eggs are handled, prepared, and served at retail establishments. In addition, the agency intends to propose specific requirements for retail establishments that serve populations most at-risk of egg-related illness (i.e., the elderly, children, and the immunocompromised).

Statement of Need:

FDA is proposing regulations as part of the farm-to-table safety system for eggs outlined by the President's Council on Food Safety in its Egg Safety Action Plan to require that shell egg producers implement SE risk reduction plans at the farm and that retail establishments institute certain egg-relevant provisions of the 1999 Food Code. FDA intends to propose these regulations because of the continued reports of outbreaks of foodborne illness and death caused by SE that are associated with the consumption of shell eggs. The agency believes these regulations can have significant effect in reducing the risk of illness from SE-contaminated eggs and will contribute significantly to the interim public health goal of the Egg Safety Action Plan of a 50 percent reduction in egg-related SE illness by 2005.

Summary of Legal Basis:

FDA's legal basis for the proposed rule derives in part from sections 402(a)(4), and 701(a) of the Federal Food, Drug and Cosmetic Act (FDCA)((21 U.S.C. 342(a)(4) and 371(a)). Under section 402(a)(4) of the Act, a food is adulterated if it is prepared, packed, or held in insanitary conditions whereby it may have been contaminated with filth or may have been rendered injurious to health. Under section 701(c) of the Act, FDA is authorized to issue regulations for the efficient enforcement of the Act. FDA also intends to rely on section 361 of the Public Health Service Act (PHSA), which gives FDA authority to promulgate regulations to control the spread of communicable disease.

Scientific reports in published literature and data gathered from existing voluntary egg quality assurance programs indicates that measures designed to prevent SE from entering a poultry house (e.g., rodent/pest control, use of chicks from SE-monitored breeders, and biosecurity programs) can be very effective in reducing SE-contamination of eggs and related foodborne illness.

Moreover, the use of shell eggs or egg products that have been treated to destroy SE or thorough cooking of untreated eggs in retail establishments will significantly contribute to the reduction of egg-related SE illnesses.

Alternatives:

There are several alternatives that the agency intends to consider in the proposed rule. The principal alternatives include: (1) no new regulatory action; (2) alternative testing requirements; (3) alternative on-farm mitigation measures; (4) alternative retail requirements; and (5) HAACP. FDA will consider the information that it receives in response to the public meetings in its consideration of the various alternatives.

Anticipated Cost and Benefits:

The benefits from a regulation designed to reduce the risk of SE contamination on the farm and at retail derive from better farming practices and safer handling and cooking of eggs at the retail level. While numerical estimates of benefits currently are not yet available, FDA believes that the benefits of the proposed rule will be significant. FDA plans to estimate benefits using data from the USDA Risk Assessment for SE in Eggs, the Layers '99 study of on-farm SE controls, and from other available information on the effectiveness of SE controls.

The costs of the proposed rule are expected to be over $100 million. It is likely that many farms and retail establishments would have to make significant alterations to their current practices. Furthermore, the proposed rule is likely to have a significant impact on small entities and will have effects that vary greatly by region.

Risks:

Any potential for contamination of eggs with SE and its subsequent survival or growth must be considered a very serious risk because of the possibility that such contamination, survival and growth could cause widespread foodborne illness, including some severe long-term effects and even loss of life. FDA made a decision to publish a proposed rule to require that shell egg producers have on-farm SE risk reduction plans and that retail establishments institute certain egg-relevant provisions of the 1999 Food Code based on a considerable body of evidence, literature and expertise in this area. In addition, this decision was also based on the USDA risk assessment on SE in shell eggs and egg products and the identified public health benefits associated with controlling SE in eggs at the farm and retail levels.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Rebecca Buckner
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
HFS-306
Center for Food Safety and Applied Nutrition
200 C Street SW.
Washington, DC 20204
Phone: 202 205-4081
Fax: 202 205-4422
Email: rebecca.buckner@cfsan.fda.gov

Nancy Bufano
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
HFS-306
Center for Food Safety and Applied Nutrition
200 C Street SW.
Washington, DC 20204
Phone: 202 401-2022
Fax: 202 205-4422
Email: nancy.bufano@cfsan.fda.gov

RIN: 0910–AC14

HHS—FDA

42. • PREMARKET NOTICE CONCERNING BIOENGINEERED FOODS

Priority:

Other Significant

Legal Authority:

21 USC 342; 21 USC 343; 21 USC 348; 21 USC 321; 21 USC 371

CFR Citation:

21 CFR 192; 21 CFR 592

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is proposing to require the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA is proposing that this submission be made at least 120 days prior to the commercial distribution of such foods. FDA is taking this action to ensure that it has the appropriate amount of information about bioengineered foods to help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law. The proposed action will permit the agency to assess on an ongoing basis whether plant-derived bioengineered foods comply with the standards of the Federal Food, Drug, and Cosmetic Act.

Statement of Need:

In the Federal Register of May 29, 1992 (57 FR 22984), FDA published its ''Statement of Policy: Foods Derived from New Plant Varieties'' (the 1992 policy), which clarified the agency's interpretation of the application of the Federal Food, Drug, and Cosmetic Act (the Act) with respect to human foods and animal feeds, including bioengineered foods and feeds, derived from new plant varieties. The 1992 policy provided guidance to industry on safety and other regulatory issues related to such foods. Since that time, developers have actively consulted with FDA regarding plant-derived bioengineered foods. That process has worked well, and FDA believes that it has been consulted on all plant-derived bioengineered foods and feeds currently marketed in the United States.

FDA is confident that the guidance articulated in the 1992 policy adequately addressed the scientific and regulatory issues raised by the products that were approaching commercialization in 1992. However, FDA is aware that bioengineering technology is evolving rapidly and that it is not possible for the agency to anticipate all of the novel scientific and regulatory issues that may arise as the number and nature of foods developed using the technology expand. Therefore, FDA is proposing to require a premarket notice regarding plant-derived bioengineered foods so that the agency has the appropriate amount of information about these foods to help ensure that all market entry decisions by the industry are made consistently and in full compliance with the law. The proposed action will permit the agency to assess on an ongoing basis whether these foods comply with the standards of the act. FDA is proposing that this submission be made at least 120 days prior to the commercial distribution of such foods.

Summary of Legal Basis:

FDA is authorized by section 701 of the Act (21 U.S.C. 371) to issue regulations for the efficient enforcement of the Act. This proposed rule will assist FDA in the agency's enforcement of the following provisions of the Act: section 403 of the Act (21 U.S.C. 343), which prohibits the misbranding of food; section 402 of the Act (21 U.S.C. 342), which prohibits the adulteration of food, and section 409 of the Act (21 U.S.C. 348), which establishes a premarket approval requirement for ''food additives,'' as defined in section 201(s) of the Act (21 U.S.C. 321(s)).

Alternatives:

FDA considered whether to continue with the current voluntary process or to issue the attached proposed rule. FDA has decided to issue the proposed rule because the agency is concerned that the current voluntary consultation process may not be adequate in the future to ensure that bioengineered foods introduced into U.S. commerce comply with all applicable statutory requirements. The proposed rule will enable the agency to efficiently enforce the Act and protect public health while imposing minimal burdens to the industry.

Anticipated Cost and Benefits:

For developers who would have gone through FDA's consultation process, the costs associated with the proposed required process would include only costs of the additional provisions of the proposed rule. The required process will be modeled on the experience and knowledge gained from the current consultation process, but there will be a number of new provisions that will have costs for notifiers. FDA estimates that the annual cost per notice would be $6,444 to $7,796 and that the total annual cost to the industry (assuming 8 to 20 notices per year) would be $51,551 to $154,658.

The proposed rule will help to ensure that bioengineered foods are adequately evaluated for potential allergenicity and toxicity, and for the potential that they contain a food additive. The proposed rule also will help to ensure that potential safety, nutritional, or other regulatory issues are addressed before the foods reach the market.

Risks:

FDA is aware that bioengineering technology is evolving rapidly and that it is not possible for the agency to anticipate all of the novel scientific and regulatory issues that may arise as the number and nature of foods developed using the technology expands. FDA believes that advances in biotechnology can, more often than in the past, lead to the introduction of significant changes into foods, such that they may be adulterated or require special labeling. FDA also believes that advances in identification of potentially useful genes in many different organisms can lead to more novel substances being introduced into foods that may be food additives or allergens. Further, FDA believes that as more countries abroad make use of biotechnology, more of the food we import may be bioengineered or may contain bioengineered substances about which we would not have been consulted. Thus, the agency believes that a voluntary consultation process may not be adequate in the future to ensure that bioengineered foods introduced into U.S. commerce comply with all applicable statutory requirements.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Linda Kahl
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
HFS-206
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, DC 20204
Phone: 202 418-3101
Fax: 202 418-3131
Email: lkahl@cfsan.fda.gov

RIN: 0910–AC15

HHS—FDA

FINAL RULE STAGE

43. FRUIT AND VEGETABLE JUICES: DEVELOPMENT OF HACCP AND LABEL WARNING STATEMENTS FOR JUICES

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

21 USC 321 et seq; 42 USC 264

CFR Citation:

21 CFR 120

Legal Deadline:

None

Abstract:

In an advance notice of proposed rulemaking of August 4, 1994, the Food and Drug Administration (FDA) announced its plans to consider the development of regulations establishing requirements for a new comprehensive food safety assurance program that would be based on the principles of Hazard Analysis Critical Control Points (HACCP). The new food safety program would respond to new challenges, such as new food processing and packaging technologies, new food distribution and consumption patterns, exposure to industrial chemicals and chemical waste, the increasing importation of foods, new microbial pathogens, and resource constraints. Current information shows that the most serious of these challenges is presented by food-borne pathogens. The number of recognized food-borne pathogens has broadened considerably, as has the awareness of long-term complications from certain food-borne illnesses such as arthritis, heart disease, and kidney and neurological damage. To meet such challenges, FDA intends to shift the focus of its food safety assurance program away from periodic visual inspection and end-product testing and toward prevention of food safety risks and problems, utilizing the state-of-the-art HACCP preventive approach. A first step was taken when FDA published a HACCP regulation for fish and fishery products on December 18, 1995. Consistent with FDA's HACCP efforts, USDA published a HACCP regulation for meat and poultry on July 25, 1996. FDA proposed on April 24, 1998 to adopt a HACCP regulation for the processing of juice. The agency simultaneously proposed to require a warning statement on the labels or in labeling for juice products that have not been processed to reduce, control, or eliminate the presence of harmful bacteria; the warning statement rule was finalized in July. Such labeling serves to reduce the risk of food-borne illness, pending development of a final HACCP rule for juice. As part of the development of the HACCP proposal, FDA considered information obtained during agency HACCP pilot activities, and comments and scientific and technological information relating to fresh juices provided during and after an agency public meeting on juice held on December 16 and 17, 1996. FDA held two technical scientific workshops, one November 12, 1998, in Lake Alfred, Florida and the other November 29, 1998, in Irvine, California, to discuss and clarify issues related to the implementation of the

agency's rule requiring a warning statement for certain juice products. The workshops addressed citrus juice production and the methods for measuring and validating such systems. On December 8 and 9, 1999, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) met to consider performance criteria for fresh juice. FDA specifically requested the NACMCF to make recommendations about the efficacy of surface treatments in ensuring the safety of citrus juices.

Statement of Need:

FDA is adopting regulations that would establish requirements for a new comprehensive food safety assurance program for both domestically produced and imported fruit and vegetable juices that would be based on the principles of Hazard Analysis Critical Control Points (HACCP). FDA intends to adopt a juice HACCP regulation because there have been a number of outbreaks of illnesses associated with juice products, including some directly affecting children, and because the agency believes that a system of preventive controls is the most effective and efficient way to ensure that these products will be safe.

Summary of Legal Basis:

Failure of a processor to have and implement a HACCP system will render the food products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the overall implementation of the firm's HACCP system.

Alternatives:

The principal alternative to HACCP is comprehensive current good manufacturing practices (CGMPs). FDA has concluded, based on information available at this time, that this alternative lacks the distinct advantages of a HACCP-based approach. CGMPs are not practical because they are plant-wide operating procedures and do not concentrate on the identification and prevention of food hazards.

Anticipated Cost and Benefits:

In general terms, HACCP focuses on prevention and is designed to prevent the occurrence of hazards affecting food; HACCP permits more effective and efficient oversight by Federal, State, and local governments; and HACCP appropriately places primary responsibility for ensuring food safety on the food manufacturer/distributor to analyze, in a rational, scientific manner, its production processes in order to identify critical control points and establish critical limits and monitoring procedures. FDA anticipates that costs to industry generated by implementation of HACCP would be offset in four ways: (1) by reducing the amount of food-borne illnesses (for example, total illness reduction benefits estimated to result from FDA's HACCP-based requirements for seafood regulation are between $15 and $75 million per year); (2) by increasing public confidence in the Nation's food supply; (3) by enabling U.S. food companies to compete more effectively in the world market (for example, current recommendations of the Codex Alimentarius Commission's Committee on Food Hygiene encourage the use of the HACCP system, and the European Community (EC) has begun to require that foods produced within the EC be processed under HACCP requirements); and (4) by decreasing the number of future product recalls.

Risks:

Any potential for contamination of the food supply with industrial chemicals or microbial pathogens must be considered a very serious risk because of the possibility that such contamination could be widespread, affecting whole segments of the population, causing some severe long-term effects and even loss of life. FDA made a decision to adopt a HACCP-based approach to regulate seafood, based on a considerable body of literature and expertise in this area. Likewise, FDA has reviewed current information on hazards associated with unprocessed juice, and has proposed that juice processors use HACCP in the manufacture of certain products.

Timetable:

Action	Date	FR Cite
ANPRM	08/04/94	59 FR 39888
ANPRM Comment Period End	12/02/94	
Economic Analysis for Juice HACCP and Labeling		
PRIA 05/01/98 (63 FR 24254)		
PRIA Comment Period End 06/22/98		
HACCP for Juice		
NPRM 04/24/98 (63 FR 20450)		
NPRM Comment Period End 08/07/98		
NPRM Comment Period Reopened 12/17/98 (63 FR 69579)		
NPRM Reopened Comment Period End 01/19/99		
Final Action 12/00/00		
Label Warning Statements for Juice		
Notice of Intent 08/28/97 (62 FR 45593)		
NPRM 04/24/98 (63 FR 20496)		
NPRM Comment Period End 06/21/98		
Final Action 07/08/98 (63 FR 37029)		

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

Previously reported under RIN 0905-AE60.

Agency Contact:

Shellee Anderson
Food Technologist
Department of Health and Human Services
Food and Drug Administration
HFS-306
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, DC 20204
Phone: 202 205-5023
Email: shellee.anderson@cfsan.fda.gov

RIN: 0910–AA43

HHS—FDA

44. ESTABLISHMENT REGISTRATION AND LISTING OF HUMAN CELLS AND TISSUE

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 264

CFR Citation:

21 CFR 207; 21 CFR 807; 21 CFR 1271

Legal Deadline:

None

Abstract:

This action is a continuation of FDA's approach for the regulation of human cells and tissues and is part of FDA's reinventing government initiative. The final rule requires manufacturers of human cells and tissue to register with the agency and submit a list of all such

cells and tissue. Future regulations would include the promulgation of good tissue practices (GTP) that will provide good manufacturing standards and requirements for donor screening and testing, and compliance and procedural provisions. The regulatory approach would provide a rational, comprehensive, and clear framework under which tissue processors can develop and market their products without being subjected to unnecessary regulation and without sacrificing the protection of the public health.

Statement of Need:

Presently, FDA can only approximate the numbers of manufacturers involved in the production of human cells and tissue. Recent innovations in the methods of manipulating human cells and tissues for therapeutic purposes have resulted in the rapid growth of the industry producing human cells and tissue. The growth has occurred in industry segments that normally communicate with the agency as well as in segments that have not previously had any contact with FDA. In order to characterize the industry and establish a basis for communication with that industry, FDA is requiring that all manufacturers of human cells and tissue register with FDA and submit lists of all their cells and tissues to the agency.

Summary of Legal Basis:

The Public Health Service Act (42 U.S.C. 216 et seq.) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) authorize FDA to regulate biological products and to ensure that the products are safe, pure, potent, and effective. The Public Health Service Act also contains the authority under which FDA can promulgate regulations designed to prevent the spread of communicable diseases. In order to meet these objectives, FDA must be able to identify those manufacturers participating in activities that may be subject to regulation. FDA is establishing the registration and listing as a simple and efficient means of acquiring the needed information.

Alternatives:

FDA has considered two alternatives. The first alternative would be an information collection undertaken by the agency that would be entirely dependent on voluntary compliance. FDA considers this alternative inefficient and lacking in inducements to ensure compliance.

The second alternative is to compel the registration of manufacturers and require registrants to list their cells and tissues with the agency. Such a system has been proposed to industry and gained general acceptance. Manufacturers would simply fill out an electronically available registration and listing form and fax or mail the completed form to the agency with periodic updates. No other paperwork should be required.

Anticipated Cost and Benefits:

Registration and listing will enable FDA to characterize the industry without imposing any significant procedural or monetary burdens. Registration and listing would provide effective means by which FDA can monitor the production of human cells and tissue. The costs of registration and listing are expected to be minimal because, as stated above, the process will require only the information necessary for FDA to identify the affected industry.

Risks:

FDA believes that the risks posed by requiring registration and listing of human cells and tissue are minimal. In contrast, failure to identify manufacturers involved in the production of human cells and tissue would subject the public to the great and avoidable risk of contracting debilitating communicable diseases. Without any mechanism to target regulations intended to reduce the risk of transmission of communicable diseases through the use of human cells and tissue, FDA's oversight of the industry would be severely hindered and the protection of the public health jeopardized.

Timetable:

Action	Date	FR Cite
NPRM	05/14/98	63 FR 26744
NPRM Comment Period End	08/12/98	
Final Action	02/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Valerie A. Butler
Consumer Safety Officer
Department of Health and Human Services
Food and Drug Administration
Suite 200N (HFM-17)
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448
Phone: 301 827-6210

RIN: 0910–AB05

HHS—Health Care Financing Administration (HCFA)

PROPOSED RULE STAGE

45. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (HCFA-3818-P) (SECTION 610 REVIEW)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 1395rr

CFR Citation:

42 CFR 400; 42 CFR 405; 42 CFR 406; 42 CFR 409; 42 CFR 410; 42 CFR 412; 42 CFR 413; 42 CFR 414; 42 CFR 489; 42 CFR 494

Legal Deadline:

None

Abstract:

This proposed rule would revise the current conditions for coverage for end stage renal disease (ESRD) facilities approved to provide ESRD service under Medicare. It would update the conditions to reflect developments in technology and equipment, emphasize the total patient experience and develop performance expectations for the facility that result in quality, comprehensive care for the dialysis patient.

Statement of Need:

Section 1881(b)(1) of the Social Security Act stipulates that payment is made to individuals, providers of services, and renal dialysis facilities

that met the requirements for institutional dialysis facilities and supplies that are determined by the Secretary. These requirements are the ESRD conditions for coverage.

Our decision to propose major changes to the existing conditions is based on several considerations. Revising the ESRD requirements is part of HCFA's effort to move towards a patient outcome-based system that focuses on quality assessment and performance improvement. We believe that revising the conditions will encourage improved outcomes of care for beneficiaries. The ESRD conditions for coverage have not been comprehensively revised since their inception in 1976. The existing requirements emphasize the policies and procedures that must be in place to support good patient care, and they focus on the facility's capacity to furnish care rather than on the actual provision of quality care to patients and the outcomes of that care. In addition, the revised conditions will implement section 4558(b) of the Balance Budget Act of 1997, which requires the Secretary to develop and implement a method to measure and report on the quality of renal dialysis services provided under Medicare.

During the 1980s and 1990s, major changes took place in the delivery of services to dialysis patients, and these advances are not reflected in the existing requirements. Thus, we have concluded that significant revisions to the conditions for coverage for ESRD facilities are essential. The regulation would have an emphasis on the patient's total experience with dialysis. The proposed changes, which were undertaken in a collaborative effort with the renal community, reflect improvements in standard care practices, the use of more advanced technology and equipment, and most notably, the adoption of quantifiable performance measures that are viewed in the renal community to be related, at least in part, to the quality of care provided to dialysis patients.

Following publication of the proposed rule, we will consult further with the industry.

Summary of Legal Basis:

Section 1881(b)(1) of the Act authorizes the Secretary to prescribe health and safety requirements (known as conditions for coverage) that a facility providing dialysis and transplantation services must meet to qualify for Medicare reimbursement. In addition, section 1881(c) of the Act establishes ESRD network areas and network organizations to assure that dialysis patients are provided appropriate care. The requirements from section 1881(b) and (c) are implemented in regulations at 42 CFR part 405, subpart U, Conditions for Coverage for ESRD Facilities.

Section 1138(b)(1)(D) of the Act requires hospitals to be members and abide by the rules and requirements of the Organ Procurement and Transplant Network. Section 1861(s)(2)(F) of the Act describes ''medical and other health services'' covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, and section 1862(a) of the Act specifies the exclusion from coverage.

Section 1861(e)(9) of the Act requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution.

Alternatives:

In the past, HCFA has revised sections of the ESRD regulations. However, we have determined that a complete and thorough revision would be a more effective mechanism for developing a comprehensive approach to quality care for the dialysis patient. In addition, this approach provides greater potential for successful implementation. Another option is to update the current regulations and maintain the process-oriented standards without focusing on patient outcome. However, for the reasons discussed, we believe it is important to move forward with a proposed regulation that is patient-centered and intended to stimulate improvements in processes and outcomes of care.

Anticipated Cost and Benefits:

The purpose of this proposed rule is to ensure that ESRD beneficiaries are receiving quality care dialysis and transplantation. We believe that revised regulations are necessary to ensure that all facilities are using the most effective technology and equipment. The primary benefit of updating the conditions for coverage is the development of performance expectations for the facility that would result in the comprehensive, integrated care and outcomes the patient needs and wants. As a result, the beneficiaries would receive an improved quality of care. The revised regulations would also address the issue of adequacy of dialysis, which would have a significant impact on ensuring that patients are not being under-dialyzed.

Items that have the potential to affect the cost of data gathering, infection control, and achieving the specified outcome measure. However, at this time the cost or savings to the Medicare program have not yet been established, but costs should not be significant.

Risks:

If the ESRD conditions are not updated, our regulations will not reflect new developments in the industry, thereby denying the improved protections to patients' health care that would result from this proposed rule.

Timetable:

Action	Date	FR Cite
NPRM	04/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions, Businesses, Organizations

Government Levels Affected:

None

Agency Contact:

Robert Miller
Department of Health and Human Services
Health Care Financing Administration
S3-02-01
Office of Clinical Standards and Quality
7500 Security Boulevard
Baltimore, MD 21244-1850
Phone: 410 786-6797
Email: rmiller1@hcfa.gov

RIN: 0938–AG82

HHS—HCFA

46. CRITERIA FOR MEDICARE COVERAGE OF HEART, LIVER, AND LUNG TRANSPLANTS (HCFA-3835-P)

Priority:

Other Significant

Legal Authority:

42 USC 1302; 42 USC 1395hh

CFR Citation:

42 CFR 482

Legal Deadline:

None

Abstract:

The rule establishes conditions of participation for facilities to perform Medicare-covered transplants.

Statement of Need:

HCFA's present criteria for heart, liver and lung transplantation centers were developed at a time when the Department's policies were intended to promote long-term survival of transplanted organs through use of patient selection policies that avoided selection of high risk patients and use of unadjusted actuarial survival as a measure of outcome and experience. More than 64,000 Americans are waiting for organ transplants, yet only about 20,000 receive organs annually. About 4,000 persons die each year waiting for an organ to become available. We consider of paramount importance our role in promoting awareness of the organ transplant situation, encouraging increased organ donation, fostering proper stewardship of this scarce national resource and ensuring that Federal policies result in equitable distribution of organs. While the goal of promoting long-term survival is laudable, we have subsequently concluded that such criteria deter transplantation of high risk patients, may not promote equitable distribution of organs, and may potentially increase deaths awaiting transplant.

The existing transplant notices address patient selection, patient management, commitment, facility plans, experience and survival rates, maintenance of data, organ procurement, laboratory services and billing. All policies require facilities to have a minimum of two years transplantation experience prior to applying for Medicare approval. The issue of setting the standards for Medicare-approved transplant facilities is complex and difficult. On one hand, we want to ensure that Medicare beneficiaries are treated only in facilities which provide quality care. However, as we limit the number of centers we approve, we could create limited access to this lifesaving technology. We strive to strike a balance between organ allocation and quality of care. While we expect facilities to continue to be responsible for appropriate organ transplant policies and protocols for these components, we do not believe it is essential for facilities to report to us on the details of these polices. We strongly believe that successful organ transplantation requires the skills and experience of an interdisciplinary team. Therefore, we intend to focus regulations on the actual care being furnished and outcomes of that care. Consequently, we are proposing to evaluate facility survival rates and experience. We propose to retain only requirements that are directly related to patient outcomes or that are necessary for data purposes. These requirements are: (1) Volume - performed 20 transplants minimum during past 4 complete calendar years; (2) Data submission - data on transplant number, date of transplant, patient diagnosis, patient status, donor types, date of most recent ascertained survival, length of survival over the past 4 years; (3) Outcomes - unadjusted actuarial 1-year patient survival is equal to or greater than the mean risk adjusted 1-year patient survival for all transplant centers in the Nation less 10 percent points calculated during the last reapproved period. We believe these standards requirements are in concert with the Department's commitment to the equitable organ allocation initiative.

In developing this proposed rule, HCFA has given serious consideration to the recommendations from the Institute of Medicine (IOM) as well as from the panel of the HCFA Town Hall Meeting held in December, 1999. These recommendations have captured the latest thinking in outcome measures of transplant centers and they entail, aspects of facilities linked to coverage, methodologies for measuring outcomes at transplant centers, data used for approving centers and thresholds for approving centers.

Summary of Legal Basis:

Section 1102 authorizes the Secretary to make and publish rules and regulations, as may be necessary to the efficient administration of the functions with each is charged under the Act. Section 1871 of the Act states, ''The Secretary shall prescribes such regulations as may be necessary to carry out the administration of insurance programs under this title.'' Given the concern that the Department has in ensuring proper stewardship of the Nation's limited organ supply and the concern that we have in ensuring Medicare beneficiaries are afforded high quality health care, we believe it is appropriate for the Secretary to use this broad authority to regulate Medicare payment for organ transplantation.

Alternatives:

For the most part, Medicare transplant center criteria have been implemented through a series of notices in the Federal Register. The exception is the kidney transplant criteria that have been implemented at 42 CFR part 405, subpart U. The use of Federal Register notices to announce the criteria has proven difficult for hospitals desiring to become Medicare approved transplant centers. Hospitals have difficulty in researching the approved criteria, and once it is located, do not know if it is current. We believe it is important to codify the requirements for Medicare approval of transplant centers in regulations. Therefore, we are proposing to include the transplant center criteria as a component of the hospital conditions of participation, so that the criteria for all five transplant types (heart, liver, lung, kidney and pancreas) are located in the same area, for ease of reference and understanding. Another option is to update the current scattered transplant policies and maintain the process-oriented standards without focusing on patient outcomes. However, based on the rationale discussed, we believe it is important to promulgate this rule to fulfill our commitment to equitable organ allocation and optimal patient outcomes.

Anticipated Cost and Benefits:

The expected benefits from the proposed rule include easy references and enhancement of better understanding of the criteria by facilities, improved patient outcomes, and it would facilitate the most equitable and medically effective use of organs that are donated in trust for transplantation.

We have not yet quantified the costs. Response to the NPRM should help to determine the cost of this regulation.

Risks:

If the CoP: Criteria for Approval of Facilities to Perform Medicare-Covered Transplants is not promulgated, our current transplant policies will not allow us to take advantage of continuing advances in the health care delivery field, or to keep current with growing demands for services, and the distribution of organs will remain inequitable.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

Federalism:

Undetermined

Agency Contact:

Marty Abeln
Department of Health and Human Services
Health Care Financing Administration
Center for Health Plans and Providers
7500 Security Boulevard
Baltimore, MD 21244-1850
Phone: 410 786-1032

Kathy Linstromberg
Department of Health and Human Services
Health Care Financing Administration
7500 Security Boulevard
Baltimore, MD 21244
Phone: 410 786-8279

Eva Fung
Health Insurance Specialist
Department of Health and Human Services
Health Care Financing Administration
S3-06-6
7500 Security Boulevard
Baltimore, MD 21244-1850
Phone: 410 786-7539

RIN: 0938–AH17

HHS—HCFA

47. ● REVISIONS TO MEDICAID UPPER PAYMENT LIMIT REQUIREMENTS FOR HOSPITAL, NURSING FACILITY, INTERMEDIATE CARE FACILITY SERVICES FOR THE MENTALLY RETARDED AND CLINIC SERVICES (HCFA-2071-P)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1902(a)(30)

CFR Citation:

42 CFR 447

Legal Deadline:

None

Abstract:

This rule would amend our regulations about the Medicaid upper payment limit (UPL) for inpatient hospital services, nursing facility services, intermediate care facility services for the mentally retarded, outpatient hospital services and clinic services. For each type of Medicaid service, current regulations place an upper limit on overall aggregate payments to all facilities and, for inpatient services a separate aggregate upper limit on payments made to State-operated facilities. This proposed rule would establish additional aggregate upper limits that would apply to payments made to all other types of government facilities that are not State-owned or operated facilities. The proposed upper limits are necessary to ensure State Medicaid payment systems promote economy and efficiency.

Statement of Need:

On February 18, 1986, we published a proposed rule in the Federal Register (51 FR 5728) to clarify and change the upper payment limit requirement to address the application of the upper payment limit to States that had multiple payment rates for the same class of services. Using the flexibility permitted under the Boren Amendment revisions to section 1902(a)(13) of the Act, many States changed their payment methodologies, to set different payment levels and payments to providers who provided the same type of care. States could substantially increase payments to one group of providers if they could offset the increased payments by making lower payments to another group of providers.

In the final rule published in the Federal Register (52 FR 28141) on July 28, 1987, we addressed the differential rate issue in the context of State-operated facilities because several audits had revealed that the circumstances of State-operated facilities resulted in a lack of incentives to curb excessive payments. Because costs not reimbursed by Medicaid or other liable payers would be borne entirely by a State, States had no reason to adopt cost effective payment methodologies for State-operated facilities. In contrast, States had a strong incentive to use cost effective methodologies for private providers, since payments to those providers would not ultimately reduce State expenditures. To ensure payments to State-operated facilities would be consistent with efficiency and economy, the final rule applied the Medicare upper limit test to State-operated facilities.

In this proposed rule, we would expand the application of upper payment limits to address an emerging problem of excessive State payment rates for Medicaid services furnished by local government providers. The changes we propose would result in three upper limit requirements that would limit Medicaid payments for inpatient hospital services, nursing facility services, intermediate care facility services for the mentally retarded, outpatient hospital services, and clinic services. For each Medicaid service category, State plans would have to comply with: (1) an upper limit on overall aggregate payments; (2) an upper limit on aggregate payments to State-owned or operated facilities; and (3) an upper limit on aggregate payments to all other types of Government-owned or operated facilities. The limits would continue to be based on Medicare payment principles. We believe these changes are necessary to ensure that States adopt payment methods and standards that result in rates that are consistent with efficiency and economy.

Under sections 1902(a)(13) and 1902(a)(30) of the Act, States have the flexibility to establish different payment methodologies to pay for the same type of inpatient services; that is, inpatient hospital services, nursing facility services, or intermediate care facility services for the mentally retarded. Section 4711 of the Balanced Budget Act of 1997(BBA)(Pub. L. 105-33) amended section 1902(a)(13) of the Act to increase State flexibility in rate setting by replacing the substantive requirements of the Boren Amendment with a new public process. Under section 4711 of the BBA, States have flexibility to target rate increases to particular types of facilities so long as the rates are established in accordance with the new public process requirements. While a similar public process requirement does not apply to rates set for outpatient hospital services or clinic services, under our previous interpretation of section 1902(a)(30) of the Act, States could also target enhanced rates to particular facilities, provided aggregate State payments for these type of services were within the upper limit.

It is apparent that a single upper limit on overall aggregate payments is not sufficient to ensure cost-effective rates, because it does not control State incentive to make excessive payments to certain facilities. Because our previous refinement to the upper payment limit was specific to State-operated facilities, States currently are permitted to establish payment methodologies that result in excessive payments to other types of government facilities such as county or city-operated facilities. We recently reviewed several State proposals that would pay county providers at levels several hundred times in excess of the

reasonable costs they incur as well as in excess of State payment levels set to obtain the same services from non-public facilities. Since these government facilities are not State-operated, Medicaid service payments to them are limited only by a State's overall aggregate expenditure for each type of Medicaid service as established under sections 447.272(a) and 447.321. Inpatient services are subject to the requirements in section 447.272(a) and outpatient services are subject to the requirements in section 447.321.

By developing payment systems for proprietary and nonprofit facilities that limit payments to more cost-effective operations, States can set rates that pay county or city facilities more than the actual costs they incur in providing covered services to Medicaid eligible individuals. Payments to these Government-owned or operated facilities as a group may substantially exceed amounts that would be determined reasonable under Medicare payment principles. Because these facilities are public entities, State funds can be transferred from those facilities (or the local government units that operate those facilities) to the State. Essentially, through such an arrangement, a State can increase Federal funding with no net increase in State expenditures. This has the effect of circumventing Federal requirements for actual expenditures and effectively may result in net provider payments that are completely Federally financed.

To correct and prevent these situations, we are proposing to revise the regulations at sections 447.272(b) and 447.321 to establish additional upper limits that would result in all payments to Government-owned or operated facilities being subject to upper payment limits.

We recognize that the new upper payment limits we are proposing could disrupt State budget arrangements, therefore our proposed changes will solicit comments on a transition period for States that have approved rate enhancement payment arrangements that exceed the new UPL.

Summary of Legal Basis:

Section 1902(a)(30) of the Act requires a State plan for medical assistance to certain methods and procedures to assure payments for care and services are consistent with efficiency, economy and quality of care. This provision provides authority for specific upper payment limits set forth in Federal regulations at 42 CFR part 477.

Alternatives:

Section 1902(a)(30) of the Act requires, in part, that Medicaid service payments be consistent with efficiency and economy. In addition to the interpretation we are proposing in this notice of proposed rulemaking, we considered several other alternatives to ensure Medicaid service payments are consistent with economy and efficiency. We also considered regulating State sources of funding. In this section, we will explain these other alternatives and why we are not proposing them.

Facility-Specific Upper Payment Limit. Under this option, Medicaid spending would be limited on a provider-specific application of Medicare payment principles. FFP would not be available on the amount of Medicaid service payment in excess of what a provider would have been paid using Medicare payment principles. Such limits would be applied to all institutions, or just to public institutions where the incentives for over-payment are significant. While a facility-specific limitation may be the most effective method to ensure State service payments are consistent with economy and efficiency, when balanced against the additional administrative requirements on States and the Congressional intent for States to have flexibility in rate setting, we are not sure that the increased amount of savings, if any, justifies this approach as a viable option.

Government-Owned or Operated Upper Limit. This proposal would limit, in the aggregate, the amount of payment States can make to public providers. Under this proposal, State and local government providers would be grouped together and payments to them as a group could not exceed an aggregate limit. The aggregate limit would continue to be based on Medicare payment principles. This option, relative to upper payment limitations we are proposing, would have allowed States to exercise more flexibility granted to them in the rate setting process. While this option permits more flexibility, we believe the aggregation of Medicaid service payments by all types of government providers would have the unintended consequence of reopening differential rate issues between State facilities and other types of government facilities.

Intergovernmental Transfers (IGTs). Because in many cases we believe there is a connection between excessive payments and IGTs, we gave some limited consideration to formulating policy with respect to them. Generally, States have genuine incentive to set Medicaid service rates at levels consistent with economy and efficiency since they share the financial burden with the Federal Government. We believe that the use of IGTs to move funds between government entities is interfering with the normal incentive for States to set reasonable service rates. However, we note that there are statutory limitations placed on the Secretary which limit the authority to place restrictions on IGTs. In light of statutory barriers to place restrictions on IGTs, we are not proposing any changes to current rules or policies pertaining to IGTs at this time. We also note that the Office of the Inspector General is examining rates paid to public facilities, the prevalence of intergovernmental transfers, and the use of funds that are transferred.

We will invite comment on these alternatives we considered and on other possible approaches for achieving our objective to ensure Medicaid service payments are consistent with efficiency and economy.

Anticipated Cost and Benefits:

We are unable to provide a specific dollar estimate of the economic impact this proposed regulation will have on State and local governments and Medicaid participating health care facilities due to data limitations and State behavioral responses. This proposed regulation does not reduce the overall aggregate amount States can spend on Medicaid services or place a fixed ceiling on the amount of State spending that will be eligible for Federal matching dollars. Under the proposed limitations, States will be able to set reasonable rates as determined under Medicare payment principles for Medicaid services furnished by public providers to eligible individuals. The amount of spending permitted under the proposed limits will vary directly with the amount of Medicaid services furnished by public providers to eligible individuals. While the proposed regulation does not affect the overall aggregate amount States can spend, by setting an upper payment limit for government providers, it may impact how States distribute available funding to participating health care facilities.

Risks:

We do not believe States will continue to set excessive payment rates for Medicaid services furnished by government providers. Generally, discontinuing an expenditure should

not result in new costs, unless the State has to fund the portion of the expenditure that is no longer federally funded with all State and local dollars. There are no Federal requirements under the Medicaid statute that mandate States to make these type of payments to Medicaid public providers and therefore we do not believe the proposed limits have any unfunded mandate implications.

We anticipate that the majority of State Medicaid programs will be unaffected by the upper payment limits we are proposing. With respect to affected States, to some degree we will be limiting flexibility in the management of their Medicaid programs. If these States wish to continue to make payments in excess of the proposed limits, they will have to fund the amount in excess with only State and local resources. In the absence of FFP, we anticipate States will reinvest these resources to support other Medicaid activities to take advantage of and maintain Federal resources. Should States realign their payment systems or divert State matching dollars to support other Medicaid activities, the total amount of available Federal funds should remain unchanged.

Timetable:

Action	Date	FR Cite
NPRM	10/10/00	65 FR 60151
Final Action	02/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

State, Local

Agency Contact:

Robert Weaver
Health Insurance Specialist, Medicaid Bureau
Department of Health and Human Services
Health Care Financing Administration
C4-16-13
7500 Security Boulevard
Baltimore, MD 21244-1850
Phone: 410 786-5914

RIN: 0938–AK12

HHS—HCFA

48. ● PAYMENT FOR CLINICAL PSYCHOLOGY TRAINING PROGRAMS AND PHYSICIAN ASSISTANT TRAINING PROGRAMS (HCFA-1089-P)

Priority:

Other Significant

Legal Authority:

Social Security Act, sec 1861(v); Social Security Act, sec 1886(a)(4); PL 105-33

CFR Citation:

42 CFR 413.85

Legal Deadline:

None

Abstract:

This proposed rule would revise our policy on Medicare payment for approved nursing and allied health education programs to permit payment for the costs incurred by a provider for the clinical training of students enrolled in a clinical psychology training program or a physician assistant training program. Consistent with the Conference Agreement language in the Conference Report accompanying the Balanced Budget Act of 1997 (Public Law 105-33), these clinical training costs would be paid separately on a reasonable cost basis pursuant to sections 1861(v) and 1886(a)(4) of the Social Security Act.

Statement of Need:

We believe we should expand existing Medicare policy to include payment for the hospital-based training of this allied health specialty because it plays an essential role in providing quality health care to Medicare beneficiaries.

Summary of Legal Basis:

Consistent with the Conference Agreement language in the Conference Report accompanying the Balanced Budget Act of 1997 (Public Law 105-33), the clinical training costs of students enrolled in a clinical psychology training program would be paid to hospitals separately on a reasonable cost basis in accordance with sections 1861(v) and 1886(a)(4) of the Social Security Act.

Alternatives:

To the extent possible, we were able to consider and incorporate the recommendations from various industry groups and affected parties.

Anticipated Cost and Benefits:

Actuarial estimates indicate that the minimal annual costs to the Medicare program associated with payment for the clinical training portion of clinical psychology training programs would be approximately $30 million the first year after payments begin and may grow to $50 million by the 5th year.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Tzvi Hefter
Center for Health Plans and Providers
Department of Health and Human Services
Health Care Financing Administration
C5-08-27
7500 Security Boulevard
Baltimore, MD 21244-1850
Phone: 410 786-1304

RIN: 0938–AK15

HHS—HCFA

49. ● PROSPECTIVE FEE SCHEDULE FOR AMBULANCE SERVICES (HCFA-1002-P)

Priority:

Other Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

PL 105-33, sec 4531(b)

CFR Citation:

42 CFR 410

Legal Deadline:

Final, Statutory, January 1, 2002.

Abstract:

The Balanced Budget Act (BBA) of 1997 requires that the Secretary establish a fee schedule for ambulance services through negotiated rulemaking. The fee schedule is to be effective beginning with services furnished on or after January 1, 2000. However, other

statutory obligations and the scope of systems changes required to implement the ambulance fee schedule were so numerous as to make it impossible for us to accomplish this concurrent with the critical work that we and our contractors had to perform to assure that our respective systems were compliant with the year 2000 requirements. Therefore, since we were unable to implement the ambulance fee schedule on January 1, 2000, we have delayed implementation of the fee schedule for ambulance services until January 1, 2001. This action is in keeping with our objective to have the ambulance fee schedule become effective as soon as possible after the January 1, 2000 statutory date; given our year 2000 activities and our other statutory obligations to implement various revised payment systems in calendar year 2000. In addition to setting the payment rates, the Secretary is to ensure that the aggregate amount of payment made for ambulance services in 2001 may not exceed the amount of payment that would have been made absent the fee schedule. This is a cap on payment, not a budget neutrality adjustment. Negotiations were conducted by a committee chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). We used the services of an impartial conveyer to help identify interests that would be significantly affected by the proposed rule (including residents of rural areas) and the names of persons who were willing and qualified to represent those interests. The Negotiated Rulemaking Committee on the Medicare Ambulance Services Fee Schedule consisted of national representatives of interests that were likely to be significantly affected by the fee schedule. To the extent that this proposed rule accurately reflected the Committee Statement as signed on February 14, 2000, each member to the Committee agreed not to comment on those issues on which consensus was reached.

Statement of Need:

The establishment of this fee schedule is required by section 4531 of the BBA. In going through the negotiated rulemaking process, a fairer payment system will be implemented that is consistent with the services furnished and that takes into account the variations caused by regional and operational differences among ambulance companies.

Summary of Legal Basis:

Section 4531 of the BBA requires the establishment of this fee schedule.

Alternatives:

Because section 4531 of the BBA requires the establishment of this fee schedule, no alternatives to this regulation exist.

Anticipated Cost and Benefits:

There is an anticipated savings of $65 million, which will be attributed to the savings that would have occurred, if the HCFA proposed regulation published on June 17, 1997 at 62 FR 32715 had been implemented in final. These savings derived from the proposal to pay for ambulance services furnished, rather than paying for the more expensive advanced life support (ALS) level of service solely because an ALS vehicle was used, even if no ALS service was furnished.

Benefits include establishing a fee schedule that will be commensurate with the services furnished, and will take into account the regional and operational variations in providing ambulances. The current reasonable charge/reasonable cost systems do not result in a fair geographic variation in payment allowances, since some areas receive two to three times the payment of other areas for the same services.

Risks:

Failing to implement the Medicare ambulance fee schedule would perpetuate an inequitable payment system that sometimes overpays and other times underpays for this critical aspect of medical care. The current system also has unintentional incentives to provide inefficient ambulance services in some areas, and inadequate ambulance services in areas of low population.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Nancy Archer
Office of Clinical Standards and Quality
Department of Health and Human Services
Health Care Financing Administration
S3-05-27
7500 Security Boulevard
Baltimore, MD 21244-1850
Phone: 401 786-0596

RIN: 0938–AK30

HHS—HCFA

50. ● ELIMINATION OF APPLICATION OF FEDERAL FINANCIAL PARTICIPATION LIMITS (HCFA-2086-P)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

42 USC 1396b(f); 42 USC 1396a(r)(2)

CFR Citation:

42 CFR 435.601; 42 CFR 435.1007

Legal Deadline:

None

Abstract:

This rule eliminates the current requirement that limits on Federal Financial Participation (FFP) must be applied when States use less restrictive income methodologies than those used by related cash assistance programs in determining eligibility for Medicaid.

This regulatory change is necessary because the current regulatory interpretation of how the FFP limits apply to income methodologies under section 190(r)(2) of the Social Security Act (the Act) unnecessarily restricts States' ability to take advantage of the authority to use less restrictive income methodologies under that section of the statute. While the enactment of section 1902(r)(2) of the Act could be read in the limited manner embodied in current regulations, the enactment of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 calls into question the current regulations approach.

Statement of Need:

States have noted that the application of the FFP limits to less restrictive income methodologies unreasonably limits their flexibility to expand Medicaid eligibility and simplify program administration by modifying cash assistance financial methodologies that do not work well in the Medicaid

context. Thus, this change will give States needed additional flexibility in setting Medicaid eligibility requirements. Even though section 1902(r)(2) was derived from the Deficit Reduction Act (DRA) of 1984 moratorium, its own legislative history did not contain any similar discussion of its interaction with the FFP section 1903(f) limits. As such, we do not believe it is necessary to consider the legislative history of DRA to be determinative of Congressional understanding of the operation of section 1902(r)(2).

Summary of Legal Basis:

In determining financial eligibility of individuals for the Medicaid program, State agencies must apply the financial methodologies and requirements of the cash assistance program that is most closely categorically-related to the individual's status. Our regulations set forth the requirements for State agencies applying less restrictive income and resource methodologies when determining Medicaid eligibility under the authority of section 1902(r)(2) of the Act. The current regulation provides that when States use less restrictive income methodologies under section 1902(r)(2), the limits on FFP in section 1903(f) of the Act apply. We are proposing to amend the regulation to eliminate the requirement that FFP limits apply to less restrictive income methodologies under section 1902(r)(2) of the Act.

The adoption of this policy would conform the application of the FFP limits under section 1902(r)(2) to the policy that we have adopted under section 1931 of the Act that less restrictive income methodologies used under section 1931 are not subject to FFP limits. We do not believe it is appropriate or necessary to continue to apply the FFP limits to section 1902(r)(2) income methodologies when they are not applied under section 1931. Further, this change gives States additional flexibility in setting Medicaid eligibility requirements.

Alternatives:

There are few alternatives to the proposed rule to consider. One alternative is to maintain the requirement that the FFP limits apply less restrictive income methodologies under section 435.601, but to allow additional disregards at a somewhat higher level than is permitted under the current regulations. However, this would not provide States the level of flexibility to operate their Medicaid programs that is provided under the proposed rule, and thus would be of only limited value. We rejected this alternative because it would not give States what they need to effectively operate their Medicaid programs, or the flexibility that Congress intended when it enacted section 1902(r)(2) of the Act.

Anticipated Cost and Benefits:

HCFA's Office of the Actuary projects a potential Federal cost of the regulation of $860 million over five years. However, the proposed change does not mandate any action or program change by the States. Any program changes are strictly at State option. Thus, the actual cost of the regulation will depend entirely on whether, and to what degree, States choose to take advantage of the increased flexibility provided by the proposed change.

We believe that this proposed rule would have a direct, positive impact on States by providing them greater flexibility in designing and operating their Medicaid programs. This proposed change has considerable support from States and others involved in the Medicaid program. We do not anticipate any public opposition to the proposed rule.

Risks:

Failure to publish this regulation would leave in place the current rule placing unreasonable limits on States' flexibility to expand Medicaid eligibility and simplify program administration by modifying cash assistance financial methodologies that do not work well in the Medicaid context.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Roy Trudel
Department of Health and Human Services
Health Care Financing Administration
C4-20-15
Center for Medicaid and State Operations
7500 Security Boulevard
Baltimore, MD 21244-1850
Phone: 410 786-3417

RIN: 0938–AK32

HHS—HCFA

FINAL RULE STAGE

51. UPDATE OF RATESETTING METHODOLOGY, PAYMENT RATES AND THE LIST OF COVERED SURGICAL PROCEDURES FOR AMBULATORY SURGICAL CENTERS EFFECTIVE FOR CALENDAR YEAR 2000 (HCFA-1885-FC)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

42 USC 13951(i)(2)(A)

CFR Citation:

42 CFR 416.61(b); 42 CFR 416.65(a)(4); 42 CFR 416.65(c); 42 CFR 416.120(c)(1); 42 CFR 416.125; 42 CFR 416.130; 42 CFR 416.140(a); 42 CFR 416.140(b); 42 CFR 488.1

Legal Deadline:

None

Abstract:

The final rule will update the criteria for determining which surgical procedures can be appropriately and safely performed in an Ambulatory Surgical Center (ASC); make additions to and deletions from the current list of Medicare covered ASC procedures based on the revised criteria; rebase the ASC payment rates using charge and utilization data collected by a 1994 survey of ASCs; refine the ratesetting methodology that was implemented by a final notice published on February 8, 1990 in the Federal Register; require that ASC payment, coverage and wage index updates be implemented annually on January 1, rather than having these updates occur randomly throughout the year; establish a payment rate for Extracorporeal Shock Wave Lithotripsy; reduce regulatory burden; and make several technical policy changes.

Statement of Need:

Although we are required by law to update the ASC list biennially, the last update to add procedures to, and delete procedures from, the list was published on January 26, 1995.

The comment period on the proposed rule was extended several times and we received over 14,000 public comments. The comment period was extended to coincide with the outpatient hospital prospective payment system (PPS) proposed rule comment period. The outpatient PPS rule had a statutory deadline, and the rule has since been published and implemented. These two rules, when taken together, will achieve a more level playing field in payment by the Medicare program for surgical services performed on an outpatient basis regardless of site of performance.

Summary of Legal Basis:

Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) provides that benefits under the Medicare Supplementary Medical Insurance program (part B) include payment for facility services furnished in connection with surgical procedures specified by the Secretary and performed in an ambulatory surgical center (ASC).

The Secretary is to review and update the list of ASC procedures biennially.

To participate in the Medicare program as an ASC, a facility must meet the standards specified under section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.25, which sets forth general conditions and requirements for ASCs.

Generally, there are two primary elements in the total cost of performing a surgical procedure: the cost of the physicians professional services for performing the procedure, and the cost of services furnished by the facility where the procedure is performed.

We are required to review and update the ASC payment amounts annually.

Alternatives:

None

Anticipated Cost and Benefits:

Undetermined

Risks:

Undetermined

Timetable:

Action	Date	FR Cite
NPRM	06/12/98	63 FR 32290
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Federalism:

Undetermined

Agency Contact:

Bob Cereghino
Program Analyst
Department of Health and Human Services
Health Care Financing Administration
C4-03-06
7500 Security Boulevard
Baltimore, MD 21244
Phone: 410 786-4645

RIN: 0938–AH81

HHS—HCFA

52. EXPANDED COVERAGE FOR DIABETES OUTPATIENT SELF-MANAGEMENT TRAINING SERVICES (HCFA-3002-P)

Priority:

Economically Significant

Legal Authority:

42 USC 1302; 42 USC 1395hh; 42 USC 1395x

CFR Citation:

42 CFR 410; 42 CFR 414; 42 CFR 424; 42 CFR 476; 42 CFR 498

Legal Deadline:

NPRM, Statutory, July 1, 1998.

Abstract:

This rule would provide for uniform coverage of diabetes outpatient self-management training services. These services include educational and training services furnished to a beneficiary with diabetes by an entity approved to furnish the services. The physician or qualified nonphysician practitioner treating the beneficiary's diabetes would certify that these services are needed as part of a comprehensive plan of care. This rule proposes the quality standards that an entity would be required to meet in order to participate in furnishing diabetes outpatient self-management training services. It sets forth proposed payment amounts that have been established in consultation with appropriate diabetes organizations. It would implement section 4105 of the Balanced Budget Act of 1997 (BBA).

Statement of Need:

Section 4105 of the BBA provided for coverage of diabetes self-management training to include services provided in nonhospital-based programs. This proposed rule would expand Medicare coverage for diabetes outpatient self-management training; define who may be a certified provider of services that may provide diabetes outpatient management training services; explain that the physician managing the patient's diabetes must certify that the services are needed under a comprehensive plan of care; and sets standards for certified providers that have been established in consultation with appropriate diabetes organizations.

Summary of Legal Basis:

Section 4105(a) of the BBA provides coverage for diabetes outpatient self-management training. Under this coverage, training would include educational and training services furnished in an outpatient setting (according to frequency standards established by the Secretary) to a beneficiary with diabetes by a ''certified provider'' that meets certain quality standards.

Alternatives:

Coverage is provided for in section 4105(a) of the BBA, therefore, no alternatives to issuing this regulation exist.

Anticipated Cost and Benefits:

Projected Budget Impact of New Benefit ($ in millions): $60 in FY 1998; $560 in FY 1999; $230 in FY 2000; $80 in FY 2001; and $80 in FY 2002. An estimate of benefits has not been established.

Risks:

If the diabetes self-management training is not implemented, our diabetic beneficiaries will not receive information for improving their long term health that would result from this rule.

Timetable:

Action	Date	FR Cite
NPRM	02/11/99	64 FR 6827
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

Federalism:

Undetermined

Agency Contact:

Betty S. Burrier
Department of Health and Human Services
Health Care Financing Administration
S3-02-01
Office of Chronic Care Insurance Policy, Bureau of Policy Development
7500 Security Boulevard
Baltimore, MD 21244-1850
Phone: 410 786-4649

RIN: 0938–AI96

HHS—HCFA

53. PROTECTION FOR WOMEN WHO ELECT RECONSTRUCTION AFTER A MASTECTOMY (HCFA-2040-IFC)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 300gg-6

CFR Citation:

45 CFR 146; 45 CFR 148

Legal Deadline:

None

Abstract:

The final rule would implement the requirements of the Women's Health and Cancer Rights Act of 1998 (WHCRA) (Pub. L. 105-277). The rules will provide protection to patients who are receiving benefits in connection with a mastectomy and who elect breast reconstruction. WHCRA provides coverage for all stages of reconstruction of the breast on which the mastectomy has been performed; surgery and reconstruction of the other breast to produce a symmetrical appearance; and coverage for prostheses and treatment of physical complications of a mastectomy, including lymphedema. Group health plans and health insurance issuers that offer medical and surgical benefits for mastectomies are subject to WHCRA's coverage requirements.

Statement of Need:

The final rule will provide needed guidance to consumers, health insurance issuers, employers and group health plans relating to coverage for breast reconstruction and related services after a mastectomy. A solicitation of comments was published in the Federal Register May 28, 1999. The Department received numerous requests from consumers, providers, and health insurance issuers for clarification of WHCRA's applicability and substantive requirements.

Summary of Legal Basis:

The Women's Health and Cancer Rights Act of 1998 (Pub. L. 105-277) was enacted on October 21, 1998 to provide protections for patients who are receiving benefits in connection with a mastectomy and who elect breast reconstruction. WHCRA was incorporated into the administrative framework established by titles I and IV of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191). In the individual health insurance market, the protections established by WHCRA applied to health insurance coverage offered, sold, issued, renewed or in effect on the date of enactment, October 21, 1998. In the group market, WHCRA's protections were effective for plan years beginning on or after October 21, 1998.

Alternatives:

None

Anticipated Cost and Benefits:

The economic impact analysis of these rules has not yet been completed. Estimates of the economic impact that will stem from these rules will be made available once analysis has been completed.

Risks:

This final rule is necessary because group health plans and health insurance issuers have been required to comply with WHCRA requirements since its enactment on October 21, 1998. Consumers, employers, health insurance issuers, and group health plans need clarification on a number of WHCRA's provisions related to coverage and the responsibilities of health insurance issuers and health plans.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/00	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Michael Bussacca
Department of Health and Human Services
Health Care Financing Administration
Center for Health Plans and Providers
7500 Security Boulevard
Baltimore, MD 21244-1850
Phone: 410 786-4602

RIN: 0938–AJ44

HHS—HCFA

54. THE CHILDREN'S HEALTH INSURANCE PROGRAM: IMPLEMENTING THE BALANCED BUDGET ACT OF 1997 (HCFA-2006-F)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 1396; PL 105-33

CFR Citation:

42 CFR 457

Legal Deadline:

None

Abstract:

This regulation establishes rules for the new Children's Health Insurance Program (CHIP). It implements sections 4901 and 4911 of the Balanced Budget Act (BBA) of 1997.

Statement of Need:

The Balanced Budget Act of 1997 (Pub. L. 105-33) creates a new title XXI of the Social Security Act to establish a Children's Health Insurance Program that supplements the Medicaid program and enables States to create a new and unique health delivery system for low-income children. This regulation will codify a series of policy guidance that has been released to the States and other interested parties over the past two years.

Summary of Legal Basis:

As established by section 4901 of the BBA, the new title XXI of the Social Security Act authorizes $41 billion over the next 10 years for States to create separate Children's Health Insurance Programs to provide health care coverage to targeted low-income children.

In order to receive reimbursement through an enhanced matching rate, States have three options in developing programs. They may expand existing Medicaid programs, create unique and separate children's health programs, or establish a combination of the two options. Within certain parameters set by the statute, States have flexibility to determine eligibility levels, develop benefit packages, and impose cost-sharing requirements. The statute also includes provisions for meeting strategic objectives, evaluation and data collection. In order to codify this authority, we have proposed implementing regulations at 42 CFR part 457.

Alternatives:

Federal payments under title XXI are based on State expenditures under approved plans that could be effective on or after October 1, 1997. The short time frame between the enactment of the BBA on August 5, 1997, and the availability of funding for States and territories required the Department to begin reviewing CHIP plans at the same time as it was issuing policy guidance to States on how to operate the CHIP program. The Department worked closely with States to disseminate as much information as possible, as quickly as possible, so States could begin to implement their new programs expeditiously. As a result, 54 States and territories have approved CHIP plans. Therefore, CHIP is now in operation prior to the completion of regulations.

Anticipated Cost and Benefits:

Estimates of the economic impact that will stem from this rule will be made available.

Risks:

This rule will formally establish the Department's policies and requirements related to the implementation of this program. It will provide States with needed information and also give them and other interested parties the opportunity to comment on the feasibility of implementing these policies. Failure to publish this rule would jeopardize our relationships with the States, advocates and providers because it would deprive them of many tools needed for establishing concrete programs.

Timetable:

Action	Date	FR Cite
NPRM	11/08/99	64 FR 60881
NPRM Comment Period End	01/07/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Organizations

Government Levels Affected:

State, Local

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Cheryl Austein-Casnoff
Department of Health and Human Services
Health Care Financing Administration
7500 Security Boulevard
Baltimore, MD 21244
Phone: 410 786-4196

Cynthia Shirk
Health Insurance Specialist
Department of Health and Human Services
Health Care Financing Administration
Phone: 410 786-6614

RIN: 0938–AJ75

HHS—HCFA

55. APPLICATION OF INHERENT REASONABLENESS TO ALL PART B SERVICES OTHER THAN PHYSICIAN SERVICES (HCFA-1908-F)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

PL 105-33, sec 4316

CFR Citation:

42 CFR 405

Legal Deadline:

None

Abstract:

This rule implements sections 1842(b)(8) and (9) of the Social Security Act, as revised by section 4316 of the Balanced Budget Act of 1997. It sets forth the process for establishing realistic and equitable payment amounts for all Medicare part B items and services (other than physician services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or grossly deficient. This rule describes the factors HCFA (or its carriers) will consider and the procedures that will be followed in establishing realistic and equitable payment amounts.

Statement of Need:

An interim final rule with comment period was published on January 7, 1998 (63 FR 687) to implement sections 1842(b)(8) and (9) of the Social Security Act, as revised by section 4316 of the Balanced Budget Act of 1997. Congress subsequently rendered this rule invalid, via section 223 of the Balanced Budget Refinement Act of 1999, by requiring that certain steps be completed before HCFA or its contractors can use the inherent reasonableness authority to adjust payment allowances. These steps will not be completed until HCFA publishes a final rule that implements the inherent reasonableness authority, responds to a July 2000 GAO report on inherent reasonableness, and responds to comments received in response to the interim final rule.

Summary of Legal Basis:

Section 223 of the Balanced Budget Refinement Act of 1999 requires the Secretary to publish this notice of final rulemaking in order to restore the inherent reasonableness authority established by section 4316 of the Balanced Budget Act of 1997.

Alternatives:

Because section 223 of the Balanced Budget Refinement Act of 1999 requires the Secretary to publish this notice of final rulemaking in order to restore the inherent reasonableness authority, no alternatives to this regulation exist. If this rule is not implemented, the inherent reasonableness authority for establishing realistic and equitable payment amounts for part B items and services, other than physician services, would not be restored.

Anticipated Cost and Benefits:

This rule establishes the process for identifying unreasonable payment amounts and replacing them with realistic and equitable amounts. It will enable future adjustments to be made to grossly excessive and grossly deficient payment amounts. There are no specific costs or savings associated with this rule because no payment adjustments are made using this rule.

Risks:

This rule will enable HCFA and the Medicare contractors to make adjustments to unreasonable payment amounts. Failing to implement this rule would eliminate the only process available for adjusting unreasonable payment amounts for many part B items and services.

Timetable:

Action	Date	FR Cite
Interim Final Rule Comment Period End	01/07/98	63 FR 687
Final Action	08/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

William J. Long
Department of Health and Human Services
Health Care Financing Administration
C4-12-18
Center for Health Plans and Providers
7500 Security Boulevard
Baltimore, MD 21228
Phone: 410 786-5655
Email: wlong@hcfa.gov

RIN: 0938–AJ97

HHS—HCFA

56. ● HOSPITAL CONDITIONS OF PARTICIPATION; ANESTHESIA SERVICES (HCFA-3049-F)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

Social Security Act, sec 1861(e)

CFR Citation:

42 CFR 416.42; 42 CFR 482.52; 42 CFR 485.639

Legal Deadline:

None

Abstract:

This final rule will change the policy on supervision of certified registered nurse anesthetists (CRNA) in administering anesthesia and will defer to State laws regarding CRNA practice. Hospitals would be free to require supervision in all incidences if they so choose, when State law allows independent CRNA practice.

Statement of Need:

The Health Care Financing Administration (HCFA) received over 20,000 comments on this issue after publication of the notice of proposed rulemaking (NPRM), December 19, 1997. Since that time, interested parties (CRNAs vs. anesthesiologists) have urged congressional action in support of their respective positions, and public debate has been heavy on either side of the issue. In addition, the public has urged HCFA to publish a final rule.

Summary of Legal Basis:

Sections 1861(e)(1) through (e)(8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861 (e)(9) of the Act specified that a hospital also must meet such other requirements as the Secretary finds necessary in the interests of the health and safety of the hospital's patients. Section 1820 of the Act contains criteria for application for States establishing a Critical Access Hospital. Sections 1832(a)(2)(f)(I) and 1833(I) provide coverage requirements for ASCs. Section 1861 (bb) of the Act provides definitions for CRNAs and their services.

Alternatives:

The only alternative available at this time would be to not publish the final rule and maintain the existing requirement. However, in consideration of public comments on the NPRM and available scientific research studies, we believe it is necessary to publish a final rule allowing flexibility by referring to State law on the issue of CRNA practice. Sound evidence does not exist to necessitate maintaining the current requirement of physician supervision of CRNAs during anesthesia delivery in every situation. Nor is there evidence that States have been negligent in their duty to regulate health professional practice or have failed to protect the safety of their citizens.

Anticipated Cost and Benefits:

There is negligible budget impact on the Medicare and Medicaid programs associated with the implementation of this final rule. This rule does not change the Medicare payment policies or fee schedules for anesthesia services provided by anesthesiologist or CRNAs. Anesthesiologists will continue to be paid as they currently are, for independent practice or for medical direction of CRNAs. CRNAs will continue to be paid on the current fee schedule that allows for independent practice.

The flexibility resulting from this rule could provide increased access to anesthesia services in some areas in hospitals, critical access hospitals (CAHs), and ASCs. It removes the burden of implementing a Federal requirement for physician supervision of CRNAs in all cases. It will allow hospitals, CAHs, and ASCs the flexibility within the authority of State licensing laws to implement best practice protocols in providing anesthesia services most associated with positive patient outcomes. Moreover, hospitals are free to exercise stricter practice standards. This provision does not lend itself to a quantitative impact estimate and we do not anticipate a substantial economic impact either in cost or savings.

Risks:

If we do not publish the final rule, we anticipate Congress may pass legislation in response to pressure from public interest groups.

Timetable:

Action	Date	FR Cite
NPRM	12/19/97	62 FR 66726
Final Rule	11/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

State

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Debbie Hattery
Health Insurance Specialist
Department of Health and Human Services
Health Care Financing Administration
S3-02-01
7500 Security Boulevard
Baltimore, MD 21244
Phone: 410 786-1855

RIN: 0938–AK08

HHS—HCFA

57. ● PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS-PHASE II (HCFA-1810-FC)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

PL 103-66, sec 13562; PL 103-432, sec 152

CFR Citation:

42 CFR 411

Legal Deadline:

None

Abstract:

In October 2000, we issued a final rule with comment period (phase I) to incorporate into regulations provisions of section 1877 that became effective January 1, 1995. The final rule with comment period (phase II) will address comments from the January 9, 1998 proposed rule concerning the ownership and investment exceptions, many of the provisions in the compensation exceptions created by Congress, and aspects of the physician referral provisions that apply to the Medicaid program. In addition, this final rule will address comments from the October 2000 final rule with comment period.

Statement of Need:

Section 1877 of the Social Security Act prohibits a physician from referring a patient to an entity for a designated health service for which Medicare might otherwise pay, if the physician or an immediate family member has a financial relationship with the entity. The statute provides for a number of exceptions to the prohibition. Section 1903(s) of the Social Security Act prohibits Federal payment of expenditures for Medicaid designated health services furnished to an individual on the basis of a referral that would result in the denial of payment for the service under Medicare. This final rule with comment will include all outstanding issues not dealt with in the October 2000 final rule with comment.

Summary of Legal Basis:

Section 6204 of OBRA 1989 established the physician referral provisions in section 1877 of the Social Security Act. The 1989 legislation prohibited a physician from referring a patient to an entity for clinical laboratory services for which Medicare might otherwise pay, if the physician or an immediate family member of the physician had a financial relationship with the entity. The statute provided for several exceptions to the prohibition. In addition, the statute imposed reporting requirements. It also prohibited an entity from presenting, or causing to be presented, a Medicare claim or bill to any individual, third party payer, or other entity for clinical laboratory services furnished under a prohibited referral, and required refunds for any amount collected under a bill for an item or service furnished under a prohibited referral. The statute also imposed civil money penalties in certain situations.

Section 1877 was amended by section 4207(e) of OBRA 1990 to clarify definitions and reporting requirements and to provide an additional exception. OBRA 1993 applied the prohibition on referrals to 10 designated health services in addition to the existing prohibition relating to clinical laboratory services. It also added new exceptions, modified some existing exceptions, and extended aspects of the law to the Medicaid program.

SSA amendments of 1994 amended the list of designated health services, changed the reporting requirements and modified some of the effective dates. The BBRA of 1999 added to the exception covering services furnished by certain prepaid plans services furnished to enrollees of coordinated care plans offered by Medicare+Choice organizations.

Alternatives:

If this final rule with comment period is not published, we would not implement either the OBRA 1993, or the SSA 1994 provisions that expanded and modified the physician referral provisions. We would not provide guidance necessary for physicians and other entities that furnish Medicare and Medicaid services to enter into appropriate financial relationships, which do not violate the physician referral provisions. In addition, neither Medicare, Medicaid, nor our beneficiaries would benefit from the protections against overutilization in the physician referral provisions.

Anticipated Cost and Benefits:

Any estimate of the effect of this final rule with comment period would be purely speculative. However, we do not anticipate that the provisions of this final rule with comment period will have a significant impact on either beneficiaries or entities that furnish designated health services. This final rule sets minimum standards for financial arrangements, while minimizing the impact on physicians' business operations. We believe that based on the statute and the October 2000 final rule with comment period, many physicians have already taken steps to ensure that their investment and employment activities meet these minimum standards.

Risks:

By statute, the prohibition on referrals for designated health services became effective on January 1, 1995. Unnecessarily delaying this final rule with comment period would cause legal uncertainty and prevent the medical community from benefiting from the provisions in this final rule. This final rule will promote compliance with Medicare and Medicaid requirements, and also prevent abuse of the Medicare and Medicaid programs and inappropriate uses of Medicare and Medicaid funds.

Timetable:

Action	Date	FR Cite
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

State, Local

Federalism:

Undetermined

Agency Contact:

Joanne Sinsheimer
Technical Assistant, CHPP
Department of Health and Human Services
Health Care Financing Administration
7500 Security Boulevard
Baltimore, MD 21244
Phone: 410 786-4620

RIN: 0938–AK31

BILLING CODE 4150–24–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (HUD)

Statement of Regulatory Priorities

The Regulatory Plan of the Department of Housing and Urban Development for Fiscal Year 2001 highlights priority regulations and policy initiatives for HUD programs that have been strengthened by Secretary Andrew Cuomo's HUD 2020 Management Reform Plan, initiated in 1997. As the Department enters its fourth year under the leadership of Secretary Cuomo, HUD has much to be proud of in the changes that have taken place at HUD under the Secretary's leadership and the accomplishments resulting from those changes. The regulations issued under the Secretary's leadership put in place many of the HUD 2020 Management reforms for HUD programs and operations. The regulations issued during the past three years, the regulations highlighted in this Regulatory Plan for Fiscal Year 2001 and in the semiannual agenda of regulations, published elsewhere in today's **Federal Register**, provide a solid basis for successor leadership to build upon and further strengthen HUD programs and operations.

From the outset of his administration, Secretary Cuomo worked to strengthen HUD as an agency by implementing reforms in HUD's management structure and in the structure and operations of HUD programs to (1) empower people and communities and (2) restore the public trust. The Secretary succeeded on both counts.

Before 1997, HUD was organized and operated strictly along program lines rather than by function. Under HUD 2020 Management Reform, HUD was reorganized by function, which regrouped program lines by mission and responsibility. This eliminated overlapping functions and duplication of work. Two examples of how functions were organized for operational efficiency can be found in HUD's new Real Estate Assessment Center and Departmental Enforcement Center, both established in 1998. The Real Estate Assessment Center assesses the physical and financial condition of HUD-assisted multifamily housing developments and public housing developments. HUD's Departmental Enforcement Center handles non-civil rights compliance enforcement actions, particularly the most serious violations committed by HUD's program participants. The functions now handled by the Real Estate Assessment Center and the Departmental Enforcement Center were previously handled by HUD's program offices, the Office of Housing, the Office of Public and Indian Housing, and the Office of Community Planning and Development. The program offices carried out these functions under independent processes, operations and requirements. HUD's reorganization not only eliminated duplication of work, allowing HUD staff to work more efficiently, but provided uniformity and consistency in treatment of program participants, to the extent permitted by law.

HUD rules issued during the past two years in response to these organizational changes reflect HUD's increased operational efficiency and also uniformity and consistency in the treatment of program participants with respect to real estate assessment and enforcement. These rules include HUD's rules on Uniform Physical Conditions Standards, Uniform Financial Reporting Standards, the Public Housing Assessment System, and Multifamily Housing's Administrative Processes for Assessment of Insured and Assisted Properties.

Consolidation of functions also has resulted in HUD's establishment of a Grants Management Center, which currently manages the competitive and formula programs of HUD's Public and Indian Housing programs. Consistent with the consolidation of HUD's grant activities is HUD's Super Notice of Funding Availability (SuperNOFA), first issued in 1998. HUD's SuperNOFA announces in one document the funding availability for the majority of HUD's competitive funded programs. The SuperNOFA consolidates and simplifies the application requirements for these programs and accelerates the funding process so that funds are awarded as early as possible in the Federal fiscal year. The success of HUD's first SuperNOFA was followed by publication of a SuperNOFA in fiscal years 1999 and 2000, and each year more HUD programs have been added to the SuperNOFA. The SuperNOFA has been enthusiastically received by HUD's clients as a better way to do business, allowing them to strategically plan for the use of Federal funds.

In addition to the reforms implemented administratively and internally by HUD, HUD was also successful in obtaining legislative reform of its public housing and Section 8 assistance programs. After six years of legislative effort and with progress evident in public housing, the Congress and the President agreed upon the Quality Housing and Work Responsibility Act of 1998 (referred to as the Public Housing Reform Act), which was signed into law on October 21, 1998. The Public Housing Reform Act is the largest overhaul of the public housing and Section 8 voucher programs in the programs' history. The Public Housing Reform Act enacted into law many of the reforms originally proposed by Secretary Cuomo's HUD 2020 Management Reform Plan, as well as by HUD's public housing bill and Congressional bills directed at revitalizing and improving HUD's public housing and Section 8 tenant-based programs.

HUD has implemented the overwhelming majority of the significant reforms provided by the Public Housing Reform Act, and HUD and its public housing agency partners have begun taking advantage of these important program changes. The Public Housing Agency Plan rule, the regulation that establishes the annual and 5-year planning mechanisms for public housing agencies, planning mechanisms long sought by HUD and its public housing agency partners, was issued as a final rule in October 1999. The Section 8 Housing Certificate Fund Allocation final rule, published in October 1999, developed through the negotiated rulemaking process, provides an efficient funding mechanism for the Section 8 tenant-based contract renewal needs of public housing agencies. The new Capital Fund Formula Allocation rule, published in May 2000, also developed through the negotiated rulemaking process, provides flexible formula funding that can be used both for renovations and replacement housing. The new Operating Fund Formula Allocation rule was published as a proposed rule in July 2000. This rule, also developed through the negotiated rulemaking process, establishes formula allocation funding of a public housing agency's operating needs.

The Public Housing Reform Act also provided for the complete merger of HUD's Section 8 tenant-based certificate and voucher programs, a program consolidation long sought by HUD. This merger provided for the new Housing Choice Voucher Program, implemented by final rule in October 1999. HUD's Section 8 Homeownership Program, recently implemented by final rule, provides a significant opportunity for low-income families to purchase their own homes and take an important step forward to economic self-sufficiency. HUD's Semiannual Agenda of Regulations, published elsewhere in this

edition of the **Federal Register**, reflects the many other Public Housing Reform Act rules that have been implemented during this past fiscal year.

During the past fiscal year, HUD reforms also led to increased homeownership protections and opportunities under HUD's Federal Housing Administration (FHA) programs. In recent years, FHA has been the driving force behind the increase in homeownership rates for first-time homebuyers and low-income and minority families. In pursuing its goal to increase homeownership rates, particularly among low-income and minority families, HUD issued in March 2000 a proposed rule that would increase the housing goal levels for the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Government Sponsored Entities or GSEs). Specifically, the rule proposed new goal levels for the purchase by the GSEs of mortgages financing low- and moderate-income housing, special affordable housing, and housing in central cities, rural areas and other underserved areas. The final rule on the new housing goal levels is included in HUD's Fiscal Year 2001 Regulatory Plan.

Accompanying its efforts to increase homeownership, FHA also has directed its efforts to protecting homeowners. In April 2000, HUD completed final rulemaking that specified its requirements and procedures for placement and removal of appraisers on HUD's Appraiser Roster. HUD maintains the Appraiser Roster to provide a means by which HUD can monitor the quality of appraisals performed on single family homes financed through FHA single family programs and to ensure that appraisers performing FHA appraisals meet high competency standards. Similar to its Appraiser Roster, FHA is strengthening its standards for placement and removal of consultants in FHA's Section 203(k) Rehabilitation Mortgage Program. Section 203(k) is FHA's primary program for the rehabilitation and repair of single family properties. A Section 203(k) lender may select a qualified independent consultant who is an expert in the field of home inspection and construction to perform various tasks required for the rehabilitation of the property. The establishment of uniform placement and removal procedures will better protect Section 203(k) borrowers and lenders. Additionally, in May 2000, Secretary Cuomo announced HUD's Fraud Protection Plan, a major consumer protection initiative to prevent millions of families who receive new FHA-insured mortgages from being victimized by predatory lending practices that can cost individual homeowners thousands of dollars each year in unnecessary costs. The plan includes, among other things, restructuring inflated mortgages, default counseling for FHA borrowers, deploying special teams to pursue unscrupulous appraisers and lenders, and removing appraisers involved with larger numbers of foreclosures.

While HUD is proud of the progress it has made in the past three years, HUD's Regulatory Plan for Fiscal Year 2001 reflects that there is still much that HUD wants to accomplish through regulatory initiatives to better serve HUD customers and better support HUD's partners. These are regulatory initiatives that reward performance, not simply impose penalties; that provide protections, not only prescribe prohibitions; and that encourage coordination and cooperation between HUD and it partners and HUD's partners and the private sector, not dissuade program participation through unnecessary command and control requirements. The regulations highlighted in this Regulatory Plan and in the Semiannual Agenda of Regulations, published elsewhere in today's **Federal Register**, are directed toward achieving these objectives. These regulations also focus on HUD's strategic goals, which are to:

1. Increase the availability of decent, safe, and affordable housing in American communities;
2. Ensure equal opportunity in housing for all Americans;
3. Promote self-sufficiency and asset development of families and individuals;
4. Improve community quality of life and economic vitality; and
5. Restore public trust.

HUD's Regulatory Priorities for Fiscal Year 2001

Regulatory Action: Capital Fund Program

HUD has run a public housing modernization program since the 1970s. By the 1990s, the program had become outmoded. Funds could be used only to modernize but not replace public housing, program rules slowed down the commitment of funds unnecessarily, and small PHAs had to apply for funding on a job-by-job basis. In the past few years, HUD worked to change this system by providing PHAs with the additional flexibility to commit funds from multiple programs, and shortening the required time for obligating funds. The Public Housing Reform Act provided the assistance HUD needed in making a more fundamental change to this outmoded modernization program. The Public Housing Reform Act creates a flexible, formula-based Capital Fund for all PHAs, which can be used for the development of replacement housing as well as modernization and management improvements.

This final rule will implement the new Capital Fund Program for the capital and management improvement needs of public housing agencies. This rule will complement the final rule for the Public Housing Capital Fund Program formula allocation funding system that was published on March 16, 2000, and provide the regulatory framework for the Capital Fund Program that will govern the use of the assistance made available from the Capital Fund formula. The new Capital Fund Program regulation will replace and remove several other rules that currently govern a PHA's use of HUD assistance including HUD's Public Housing Development and Public Housing Modernization regulations. The new Capital Fund Program regulation will adopt and expand upon the streamlined procedures and requirements initiated under the Comprehensive Grant and Comprehensive Improvement programs.

[Furthers Strategic Goals 1 and 4]

Regulatory Action: Mixed Finance Development Program

The success of partnering with the private sector to create new communities is apparent through the many new developments that have been built across the nation through mixed financing. Leveraging of private funds for public housing was first made possible for public housing agencies to use administratively in 1994, and HUD and its housing partners have taken advantage of this option to offer public housing in deconcentrated settings.

This final rule will implement important long sought changes to HUD's Mixed Finance Program made possible by the Public Housing Reform Act. This rule will also enhance the Mixed Finance Development Program by ensuring that it works in coordination and correlation with HUD's new Capital Fund Program. The rule will clarify the specific program requirements and procedures that apply to the Mixed Finance Program and will establish streamlined submission and HUD review requirements with respect to certain types of mixed finance projects

that HUD believes involve minimal risk to the investment of Federal funds in the project.

[Furthers Strategic Goals 1 and 4]

Regulatory Action: Determining Adjusted Income in HUD Programs Serving Persons with Disabilities and Requiring Mandatory Deductions for Certain Expenses and Disallowance for Earned Income

HUD is aware that the lack of accessible, affordable housing continues to be a barrier to the ability of persons with disabilities to take advantage of economic opportunities in many communities across the country. The availability of accessible, affordable housing and the location of that housing can be the key to persons with disabilities who are seeking employment to obtain employment. To minimize the barriers to accessible, affordable housing, HUD is continually examining its programs to determine ways, through administrative initiatives or legislative or regulatory changes, that may assist in breaking down these barriers. HUD has identified two changes that HUD believes will encourage and facilitate employment of persons with disabilities, and that can be implemented in several HUD programs through this rulemaking. The first change involves including additional HUD programs in the list of programs that must make certain deductions in calculating a family's adjusted income. These deductions primarily address expenses related to a person's disability, such as medical expenses or attendant care expenses. Providing for the calculation of these deductions in a family's adjusted income expands the benefits of these deductions to persons with disabilities served by HUD programs. The second change allows, in certain HUD programs, for the disallowance of increases in income as a result of earnings by persons with disabilities. HUD believes that making these deductions and earned income disallowance available to persons with disabilities through as many HUD programs as possible will assist persons with disabilities in obtaining and retaining employment, which is an important step toward economic self-sufficiency.

[Furthers Strategic Goals 2, 3 and 4]

Regulatory Action: Public Housing Demolition and Disposition

With the flexibility provided by the Public Housing Reform Act, this rule articulates and implements a new strategy for demolition and disposition of deteriorating and dilapidated public housing. This rule will implement that strategy by establishing the general and specific requirements for HUD approval of demolition and disposition applications, relocation of residents, resident participation in the form of consultation and opportunity to purchase, new requirements regarding replacement units and a new authority for a public housing agency to demolish a small number of its units without a formal application under certain circumstances. This rule, together with HUD's rules implementing the Capital Fund Program and Mixed Finance Program, will allow HUD and its public housing agency partners to transform public housing's severely distressed developments into safe, livable communities.

[Furthers Strategic Goals 1 and 4]

Regulatory Action: The Secretary of HUD's Regulation of Fannie Mae and Freddie Mac (Government Sponsored Entities) — New Housing Goal Levels

Fannie Mae and Freddie Mac are chartered by Congress as Government Sponsored Enterprises (GSEs) to provide stability in the secondary market for residential mortgages; respond appropriately to the private capital market; provide ongoing assistance to the secondary market for residential mortgages (including activities relating to mortgages on housing for low- and moderate-income families involving a reasonable economic return that may be less than the return earned on other activities) by increasing the liquidity of mortgage investments and improving the distribution of investment capital available for residential mortgage financing; and promote access to mortgage credit throughout the nation (including central cities, rural areas, and other underserved areas While the GSEs have been successful in providing stability and liquidity to certain portions of the mortgage market, the GSEs' share of the affordable housing market is substantially smaller than their share of the total conventional conforming mortgage market.

Through this final rule, the Department is establishing new housing goal levels for the purchase of mortgages by the GSEs through 2003. In accordance with the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, this rule establishes new goal levels for the GSEs for the purchase of mortgages financing low- and moderate-income housing, special affordable housing, and housing in central cities, rural areas, and other underserved areas. This rule also clarifies HUD's guidelines for counting different types of mortgage purchases toward those goals. As the GSEs continue to grow their businesses, the new goals will provide strong incentives for the two enterprises to more fully address the housing finance needs for very low-, low- and moderate-income families and residents of underserved areas and therefore more fully realize their public purpose.

[Furthers Strategic Goals 2 and 3]

Regulatory Action: The Secretary of HUD's Regulation of Fannie Mae and Freddie Mac (Government Sponsored Entities) — Prohibitions on Purchasing Certain Loans with High Costs and/or Predatory Features

In a report issued by HUD and the Department of Treasury in June 2000 titled ''Curbing Predatory Home Mortgage Lending,'' HUD and Treasury noted that by providing a source of funding, entities operating in the secondary mortgage market that purchase or securitize loans with high costs and/or predatory features may be supporting the activities of predatory loan originators. As pointed out in the HUD/Treasury report: ''While the secondary market could be viewed as part of the problem of abusive practices in the subprime mortgage market, it may also represent a large part of the solution to the problem.'' The subprime market refers to the mortgage market where most borrowers use the collateral in their homes for debt consolidation or other consumer credit purposes.

Although the GSEs currently play a relatively small role in the subprime market, they are beginning to reach out with new products in that marketplace. While both GSEs have recently pledged not to purchase loans with certain identified predatory features, the HUD/Treasury report recommended that regulatory restrictions be put in place to help curb abusive practices.

This rulemaking will establish regulatory restrictions, consistent with the GSEs' voluntary restrictions, that will prohibit the GSEs from purchasing certain loans with high costs and/or predatory features. This rule will ensure that GSEs are not supporting the activities of predatory loan originators.

[Furthers Strategic Goals 2, 3 and 5]

Regulatory Action: Prohibition of Predatory Lending Practices in HUD's Single Family Mortgage Insurance Programs

Along with the benefits that have come from the expanded availability of credit in the subprime market, there is also evidence of growing abuses in lending practices. In many neighborhoods, abusive practices threaten to erode the enormous progress that has been made over the past several years in revitalizing neighborhoods and expanding homeownership. In many instances, the consequence for borrowers is foreclosure of their homes. In a predatory lending situation, the party that initiates the loan often provides misinformation, manipulates the borrower through aggressive sales tactics and/or takes unfair advantage of the borrowers' lack of information about the loan terms and their consequences. The results are loans with onerous terms and conditions that the borrower often cannot repay, leading to foreclosure or bankruptcy.

These predatory lending practices were discussed in more detail in the HUD and Department of Treasury report titled ''Curbing Predatory Home Mortgage Lending.'' This proposed rule is issued in response to recommendations made by that report. This proposed rule would prevent property ''flipping,'' which is the practice whereby a property recently acquired is resold for a considerable profit, often with inflated value abetted by collusion with the appraiser. Additionally, this rule would seek to cap the discount points and fees that can be charged on a mortgage to be insured by FHA. The purpose of this rule is to protect borrowers from becoming unwitting victims of predatory lending.

[Furthers Strategic Goals 3 and 5]

HUD—Office of the Secretary (HUDSEC)

PROPOSED RULE STAGE

58. • DETERMINED ADJUSTED INCOME IN HUD PROGRAMS SERVING PERSONS WITH DISABILITIES: REQUIRING MANDATORY DEDUCTIONS FOR CERTAIN EXPENSES; AND DISALLOWANCE FOR EARNED INCOME (FR-4608)

Priority:

Other Significant

Legal Authority:

42 USC 1437f; 42 USC 3535(d)

CFR Citation:

24 CFR 5; 24 CFR 92; 24 CFR 200; 24 CFR 236; 24 CFR 574; 24 CFR 582; 24 CFR 583; 24 CFR 891; 24 CFR 982

Legal Deadline:

None

Abstract:

This final rule will amend HUD's regulations in part 5, subpart F, among others, to include additional HUD programs in the list of programs that must make certain deductions in calculating a family's adjusted income. These deductions primarily address expenses related to a person's disability, for example medical expenses or attendant care expenses. The purpose of this amendment is to expand the benefits of these deductions to persons with disabilities served by HUD programs not currently covered by part 5, subpart F. Second, the final rule will add a new regulatory section to part 5 to require for some but not all of these same programs the disallowance of increases in income as a result of earnings by persons with disabilities. HUD believes that making these deductions and disallowance available to persons with disabilities through as many HUD programs as possible will assist persons with disabilities in obtaining and retaining employment, which is an important step toward economic self-sufficiency.

Statement of Need:

The regulatory changes proposed by this rule represent an important step forward in helping to remove financial barriers that make it difficult for persons with disabilities who are seeking to obtain employment, and to keep employment once obtained.

Summary of Legal Basis:

Section 508 of the Quality Housing and Work Responsibility Act of 1998 (Pub.L. 105-276) amended section 3(b) of the U.S. Housing Act of 1937 to provide for certain income deductions and earned income disregard. This rule extends the benefits of these statutorily provided deductions and earned income disregard to certain HUD programs.

Alternatives:

HUD has been able to extend, administratively at times, the benefits of some measures to HUD programs not specifically identified by the statute. The deductions and the disregard of earned income finalized by this rule constitute an important step in helping persons with disabilities find and retain employment. While these kinds of benefits may be possible in the various HUD programs, greater uniformity will ensure increased applicability to persons with disabilities.

Anticipated Cost and Benefits:

The financial savings to a person with disabilities that this rule would provide presents an incentive to that person to continue working, or if not working, to seek employment. Also, owners and entities that administer the HUD assisted housing for persons with disabilities will benefit because the proposed rule provides greater uniformity in determining annual income for HUD programs that serve persons with disabilities, and likely minimize the administrative burden that results from the different requirements under different programs for persons and families in similar or identical circumstances.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	08/21/00	65 FR 50842
NPRM Comment Period End	10/20/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Patricia Arnaudo
Senior Housing Program Manager, Office of Public and Assisted Housing Delivery
Department of Housing and Urban Development
Office of Public and Indian Housing
Phone: 202 708-0744

Mary Kolesar
Director, Office of Affordable Housing Programs
Department of Housing and Urban Development
Office of Community Planning and Development
Phone: 202 708-2470

RIN: 2501–AC72

HUD—HUDSEC

59. ● THE SECRETARY OF HUD'S REGULATION OF FANNIE MAE AND FREDDIE MAC; PROHIBITING THE PURCHASE OF CERTAIN LOANS WITH HIGH COSTS AND/OR PREDATORY FEATURES (FR-4614)

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

12 USC 1451 et seq; 12 USC 1716 et seq; 12 USC 4501 et seq; 42 USC 3535(d)

CFR Citation:

24 CFR 81

Legal Deadline:

None

Abstract:

A report issued in June 2000 by HUD and the Department of Treasury entitled ''Curbing Predatory Home Mortgage Lending,'' noted that by providing a source of funding, entities that purchase or securitize loans with high cost and/or predatory features are, knowingly or unknowingly, supporting the activities of predatory loan originators. The report recommended regulatory restrictions that would prohibit the two Government-Sponsored Enterprises (GSEs), Fannie Mae and Freddie Mac, from purchasing certain types of loans with high costs and/or predatory features altogether. Through this rulemaking, HUD will establish regulatory restrictions, consistent with the GSEs' voluntary restrictions, that will prohibit the GSEs from purchasing certain loans with high costs and/or predatory features. Specifically, this rule will prohibit the GSEs from purchasing loans that come within the high-cost thresholds of the Home Ownership Equity Protection Act, loans with excessive fees, loans originated with single-premium credit life insurance, and loans with other harmful features. This rule will help to ensure that these GSEs are not supporting the activities of predatory loan originators.

Statement of Need:

While the GSEs currently play a relatively small role in the market for loans with high costs and/or predatory features, their role may continue to expand in the future. This rule will help to ensure that the GSEs are not providing funding and liquidity to support lenders that originate loans with predatory features or that employ unacceptable practices. The GSEs' Charters require them to provide ongoing assistance to the secondary market for residential mortgages, including activities relating to mortgages on housing for low- and moderate-income families and to promote access to mortgage credit throughout the Nation (including central cities, rural areas, and underserved areas). Predatory lending activities are often targeted to those families and to borrowers living in those areas, often leading to increased indebtedness and foreclosures, depriving these families of the equity in their home and weakening their neighborhoods. Financial support for such activities undermines the GSEs' Charter missions. This rule is necessary to fulfill HUD's authority and responsibility to ensure that the purposes of the Charters are accomplished.

Summary of Legal Basis:

Under section 1321 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4541) (the GSE Act), HUD has general regulatory power over each GSE and must issue such rules and regulations as necessary and proper to ensure that the GSE Act and the GSEs' Charters are accomplished. Section 1325(1) of the GSE Act requires HUD, by regulation, to prohibit each GSE from discriminating in any manner in the purchase of any mortgage because of race, color, religion, sex, handicap, familial status, age, or national origin, including any consideration of the age or location of the dwelling or the age of the neighborhood or census tract where the dwelling is located in a manner that has a discriminatory effect.

Alternatives:

The alternative of not prohibiting the GSEs from purchasing loans with high costs and/or predatory features was considered. However, after thorough examination of this issue by HUD and the Department of Treasury in their June 2000 Report, the recommendation was that regulatory restrictions should be pursued.

Anticipated Cost and Benefits:

This rule will have the benefit of helping to ensure that the GSEs are not supporting the activities of predatory loan originators, which undermine homeownership for low-income families and in underserved neighborhoods. Since the GSEs currently play a relatively small role in the market for these loans, and have already volunteered to restrict their purchases of such loans, this rule should not represent a substantial cost to the GSEs or other entities in the subprime mortgage market.

Risks:

This rule poses no risk to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Janet Tasker
Director, Office of GSE
Department of Housing and Urban Development
Office of Housing
Phone: 202 708-2224

Allen Fishbein
Senior Advisor for GSE
Department of Housing and Urban Development
Office of Housing
Phone: 202 708-3600

RIN: 2501–AC76

HUD—HUDSEC

FINAL RULE STAGE

60. SECRETARY OF HUD'S REGULATION OF FANNIE MAE AND FREDDIE MAC: PURCHASE GOALS (FR-4494)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

12 USC 1451 et seq; 12 USC 1716 to 1723h; 12 USC 4501 to 4641; 42 USC 3535(d); 42 USC 3601 to 3619

CFR Citation:

24 CFR 81

Legal Deadline:

None

Abstract:

Through this rule, the Department is establishing new housing goal levels for the purchase of mortgages by Fannie Mae and the Freddie Mac (collectively, the Government Sponsored Enterprises, or GSEs) through 2003. In accordance with the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, this rule establishes new goal levels for the GSEs for the purchase of mortgages financing low- and moderate-income housing, special affordable housing, and housing in central cities, rural areas, and other underserved areas. This rule also clarifies HUD's guidelines for counting different types of mortgage purchases toward those goals.

Statement of Need:

Regulations prior to this rulemaking, which were issued in 1995, established the GSEs' housing goals for 1995-99. Through this rule, the Secretary is establishing new goals through 2003 to reflect the Secretary's consideration of the statutory factors for establishment of these goals including current economic conditions. The new goals will provide strong incentives for the two enterprises to more fully address the housing finance needs for very low-, low- and moderate-income families and residents of underserved areas and thus, to realize more fully their public purposes. Such incentives are consistent with the Department's strategic objectives of increasing homeownership opportunities and the supply of affordable rental housing in the United States.

Summary of Legal Basis:

The Department is authorized to establish housing goals for the GSEs by the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4501 et seq.), which sets forth parameters and requirements for the housing goals and other issues addressed in this rule.

Alternatives:

The alternative of leaving the housing goals unchanged was considered. This alternative was not adopted because of HUD's responsibility to establish the housing goals in accordance with FHEFSSA and because such an approach would fail to meet HUD's strategic objectives of increasing the supply of affordable rental housing and homeownership and promoting equal housing opportunities for those protected by the law.

Anticipated Cost and Benefits:

This rule will have the benefit of increasing the number of affordable housing units for low- and moderate-income families and underserved communities through 2003. However, there is no indication that focusing the GSEs' attention on the affordable lending market would be costly for the GSEs. In fact, HUD's analysis indicates that meeting the new housing goals will have little impact on the GSEs' financial returns or on the safety and soundness of GSE operations. Additionally, increased GSE activity in the affordable lending arena should not lead to significant crowding out of traditional portfolio lenders.

Risks:

This rule poses no risk to public health, safety or the environment.

Timetable:

Action	Date	FR Cite
NPRM	03/09/00	65 FR 12632
NPRM Comment Period End	05/08/00	
Final Action	10/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Janet Tasker
Director, Office of GSE
Department of Housing and Urban Development
Office of Housing
Phone: 202 708-2224

Allen Fishbein
Senior Advisor for GSE
Department of Housing and Urban Development
Office of Housing
Phone: 202 708-3600

RIN: 2501–AC60

HUD—Office of Housing (OH)

PROPOSED RULE STAGE

61. • PROHIBITION OF PREDATORY LENDING PRACTICES IN HUD'S SINGLE FAMILY MORTGAGE INSURANCE PROGRAM (FR-4615)

Priority:

Other Significant

Legal Authority:

42 USC 3535(d); 12 USC 1709; 12 USC 1710; 12 USC 1715b; 12 USC 1715u

CFR Citation:

24 CFR 203; 24 CFR 206

Legal Deadline:

None

Abstract:

Predatory lending, whether undertaken by creditors, brokers or even home improvement contractors, involves engaging in deception or fraud, manipulating the borrower through aggressive sales tactics, or taking unfair advantage of a borrower's lack of understanding about loan terms. These practices are often combined with loan terms that, alone or in combination, are abusive or make the borrower more vulnerable to abusive practices. Predatory lending generally occurs in the subprime mortgage market, where most borrowers use the collateral in their homes for debt consolidation or other consumer credit purposes. This proposed rule would prohibit two predatory lending practices. This proposed rule would prohibit property ''flipping,'' the practice whereby a property recently acquired is resold for a considerable profit, often with inflated value abetted by collusion with the appraiser. Additionally, this rule would seek to cap the discount points

and fees that can be charged on a mortgage to be insured by HUD's Federal Housing Administration (FHA). The purpose of this rule is to protect borrowers from becoming unwitting victims of predatory lending by capping the total amount of discount points and fees that can be charged on mortgages to be insured by FHA.

Statement of Need:

A report issued in June 2000 by HUD and the Department of Treasury entitled ''Curbing Predatory Home Mortgage Lending,'' recommends proposals for legislative and regulatory action to combat predatory lending practices. The recommendations are based, in significant part, on information that HUD and Treasury gathered through the National Task Force on Predatory Lending. This proposed rule arises from the recommendations in the report.

Summary of Legal Basis:

The National Housing Act and HUD's authority under the Department of Housing and Urban Development Act authorize HUD to provide a home financing system through the insurance of mortgages that would maintain and expand homeownership opportunities, particularly to first-time homebuyers and low-income families.

Alternatives:

Nonregulatory initiatives to date have not proven to be sufficiently successful in curbing predatory lending practices. The HUD/Treasury report recommended legislative and regulatory initiatives.

Anticipated Cost and Benefits:

This rulemaking will help to reduce excessive fees and costs of home mortgages. The anticipated benefit is that the rule will help to reduce foreclosure arising from high costs mortgages.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Vance Morris
Director, Office of Single Family Program Development
Department of Housing and Urban Development
Office of Housing
Phone: 202 708-2700

RIN: 2502–AH57

HUD—Office of Public and Indian Housing (PIH)

PROPOSED RULE STAGE

62. MIXED-FINANCE PUBLIC HOUSING DEVELOPMENT (FR-4499)

Priority:

Other Significant

Legal Authority:

42 USC 1437g; 42 USC 3535(d)

CFR Citation:

24 CFR 941

Legal Deadline:

None

Abstract:

This proposed rule will implement amendments to the Department's Mixed Finance Program to reflect statutory changes enacted on October 21, 1998. Also, the rule will revise the Mixed Finance Program so that the program conforms to HUD's new Capital Fund regulations; will clarify the specific program requirements and procedures that apply to the Mixed Finance Program; and will establish streamlined submission and HUD review requirements with respect to certain types of mixed finance projects that the Department believes involve minimal risk to the investment of Federal funds in the project.

Statement of Need:

Section 539 of the Quality Housing and Work Responsibility Act of 1998 (Pub.L. 105-276) (referred to as Public Housing Reform Act) added a new section 35 to the U.S. Housing Act of 1937 to permanently authorize the leveraging of private resources in the development of public housing (the ''mixed finance'' method). The permanent framework provided by the Public Housing Reform Act and the significant changes PHRA made to the structure of the development program, necessitates a regulation to provide appropriate notice of the legal framework for the program and clear and uniform guidance for program operation.

Summary of Legal Basis:

Sections 539 and 519 of the Public Housing Reform Act, added section 35 and amended section 9 respectively, to the U.S. Housing Act of 1937 to authorize changes to the Mixed Finance Program.

Alternatives:

The Public Housing Reform Act made statutory changes to HUD's Mixed Finance Program that must be implemented through rulemaking.

Anticipated Cost and Benefits:

Costs for entities should be reduced due to the streamlined procedures and allowance for longer term planning because of the certainty to be provided through issuance of final regulations.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

David Sowell
Director, Office of Public Housing Investments
Department of Housing and Urban Development
Office of Public and Indian Housing
Phone: 202 401-8812

RIN: 2577–AC09

HUD—PIH

63. PUBLIC HOUSING CAPITAL FUND PROGRAM (FR-4507)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 1437g; 42 USC 3535(d)

CFR Citation:

24 CFR 905; 24 CFR 941; 24 CFR 968; 24 CFR 969

Legal Deadline:

None

Abstract:

This proposed rule will implement the new Capital Fund Program for the capital and management improvement needs of public housing agencies. The rule will complement the final rule for the Public Housing Capital Fund Program formula allocation funding system published on March 16, 2000 (65 FR 14422). This rule will implement the regulatory framework for the Capital Fund Program that will govern the use of the assistance made available through the Capital Fund formula. The new rule at part 905 will replace and remove several other rules that currently govern a PHA's use of HUD assistance including part 941 - Public Housing Development and part 968 - Public Housing Modernization. This proposed rule will continue and expand the streamlining of procedures and requirements initiated under the Comprehensive Grant and Comprehensive Improvement programs at part 968.

Statement of Need:

Assistance under the Capital Fund Program is the primary, regular source of funding made available by HUD to a PHA for its capital activities, including modernization and development of public housing. This final rule will implement the requirements for the use of assistance made available under the Capital Fund program. The regulations will provide the appropriate notice of the legal framework for the program, and clear and uniform guidance for program operation.

Summary of Legal Basis:

Sections 518, 519, and 539 of the Quality Housing and Work Responsibility Act of 1998 (Pub. L. 105-276) (referred to as the Public Housing Act) amended sections 9 and 5, and added section 35(g) of the U.S. Housing Act of 1937 (42 U.S.C. 1437g) to establish the Capital Fund Formula and Capital Fund Program.

Alternatives:

The Public Housing Reform Act required a formula system to be established through rulemaking to govern funding of PHAs' public housing capital needs. Guidance for administration of these funds necessitates a permanent legal framework.

Anticipated Cost and Benefits:

The costs of the program as administered with one fund from which a PHA will fund all of its capital needs is the same as under existing provisions. The benefits of having one funding mechanism for all such needs, and the provision of additional flexibility to PHAs to manage their physical assets provides increased benefits to the PHAs. Likewise, uniform program administration of these funds will provide increased benefits to the PHAs.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local

Agency Contact:

William Flood
Director, Office of Capital Improvements
Department of Housing and Urban Development
Office of Public and Indian Housing
Phone: 202 708-1640

RIN: 2577–AC16

HUD—PIH

64. ● PUBLIC HOUSING DEMOLITION AND DISPOSITION (FR-4598)

Priority:

Other Significant

Legal Authority:

42 USC 1437p; 42 USC 3535(d)

CFR Citation:

24 CFR 970

Legal Deadline:

None

Abstract:

This proposed rule will revise HUD's regulations regarding demolition and disposition of public housing projects, in accordance with section 531 of the Quality Housing and Work Responsibility Act of 1998 (Pub.L. 105-276) (referred to as the Public Housing Reform Act). This rule will establish the general and specific requirements for HUD approval of demolition and disposition applications, relocation of residents, resident participation in the form of consultation and opportunity to purchase, new requirements regarding replacement units and a new authority for a PHA to demolish a small number of their units without a formal application under certain circumstances, referred to as ''de minimis'' demolition.

Statement of Need:

Section 531 of the Public Housing Reform Act amended the provisions on public housing demolition and disposition found in section 18 of the U.S. Housing Act of 1937. These amendments changed both the general standard for approval of applications for demolition or disposition of public housing stock, and many of the specific procedures for these actions. The significant changes the Public Housing Reform Act made to demolition or disposition of public housing necessitate a regulation to provide appropriate notice of the legal framework for the program and clear and uniform guidance for program operation.

Summary of Legal Basis:

Section 531 of the Public Housing Reform Act amended section 18 of the U.S. Housing Act of 1937 to establish revised demolition and disposition requirements.

Alternatives:

Through this rulemaking, the Department will implement the Public Housing Reform Act amendments to demolition or disposition of public housing developments. Guidance about program administration necessitates a permanent legal framework rather than less formal HUD notices.

Anticipated Cost and Benefits:

The streamlining procedures for demolition and disposition of public housing provided by the statute and regulations will reduce costs for PHAs.

Risks:

This rule poses no threat to public safety, health, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

William Flood
Director, Office of Capital Improvements
Department of Housing and Urban Development
Office of Public and Indian Housing
Phone: 202 708-1640

RIN: 2577–AC20

BILLING CODE 4210–01–S

DEPARTMENT OF THE INTERIOR (DOI)

Statement of Regulatory Priorities

The Department of the Interior (DOI) is the principal steward of our nation's natural resources and guardian of many of our priceless cultural resources. We serve as trustee to Native Americans and Alaska natives and also are responsible for relations with the island territories under United States jurisdiction. As part of our duties, we manage more than 430 million acres of Federal lands, approximately 2 billion acres of the Outer Continental Shelf, and more than 57,000 buildings. In carrying out our many responsibilities we are committed to creative ideas that:

- Ensure the long-term viability of our resources
- Protect the environment in which our resources are found
- Minimize negative effects and maximize benefits to the American people.

The Department's bureaus and offices seek to ease the burdens imposed by regulations while increasing the protection of resources under their jurisdiction. Examples of this include:

- Establishing a community approach to maintaining the environmental systems that support native species. We expect this to reduce the rate at which individual species become threatened and endangered. This approach enlists the voluntary support of landowners to achieve environmental goals while potentially reducing the regulatory cost.
- Using performance-based regulations rather than process-based regulations. This gives local entities the options of using the most cost-effective method to meet the spirit and letter of the law while providing the best result for the specific instance and location.
- Incorporating scientific standards, where applicable, into regulations.
- Continuing to reduce the number of regulations and converting those that remain to plain language. This will improve the public's ability to understand regulatory requirements and will result in improved compliance.

The Department's overall goal is to maintain or improve the quality of the environment while:

- Reducing the financial burden on the general public;
- Increasing the flexibility of the public to use the best means available to ensure that the laws are met; and
- Making regulations easy to understand and administer.

This approach to improving regulations will help us better execute our mission and meet the requirements of our eight bureaus and the following objectives:

- Conserve, protect, and enhance the Nation's national parks, wilderness, and fish and wildlife resources;
- Manage, develop, and protect the quality of water resources;
- Promote economic opportunity and improve the trust assets of American Indians, Indian tribes, Alaska Natives, and people of the U.S. territories;
- Improve the Federal Government's relationship with State, local, tribal, and territorial governments; and
- Enhance America's ability to meet its needs for domestic energy and mineral resources.

Major Regulatory Areas

Among the Department's bureaus and offices, the Office of Surface Mining Reclamation and Enforcement (OSM) has the highest concentration of regulatory responsibilities. OSM, in partnership with the States and Indian tribes, has the responsibility for setting and enforcing environmental standards during coal mining and reclamation operations. Other DOI bureaus rely on regulations to implement legislatively mandated programs by focusing on the management of natural resources and public or trust lands. Some of these regulatory activities include:

- Management of migratory birds and preservation of certain marine mammals and endangered species;
- Management of dedicated lands, such as national parks, wildlife refuges, and American Indian trust lands;
- Management of public lands open to multiple use;
- Leasing and oversight of development of Federal energy, minerals, and renewable resources;
- Management of revenues from American Indian and Federal minerals;
- Fulfillment of trust and other responsibilities pertaining to American Indian tribes;
- Natural resource damage assessments; and
- Management of financial and nonfinancial assistance programs.

Regulatory Policy

How DOI Regulatory Procedures Relate to the Administration's Regulatory Policies

Within the requirements and guidance in Executive Orders 12866, 13132, and 12630, DOI's regulatory program seeks to:

- Fulfill all legal requirements as specified by statutes or court orders;
- Perform essential functions that cannot be handled by non-Federal entities;
- Minimize regulatory costs to society while maximizing societal benefits; and
- Operate programs openly, efficiently, and in cooperation with Federal and non-Federal entities.

DOI bureaus have taken the initiative in working with other Federal agencies, State, local, and tribal governments, private entities, and the general public to make our regulations easier to comply with and understand. Because regulatory reform is a continuing process that requires the participation of all affected parties, we strive continually to include all affected entities in the decision making process and to issue rules more efficiently. To better manage and review the regulatory process, we have revised our internal rulemaking guidance. Results have included:

- Increased bureau awareness of and responsiveness to the needs of small businesses and better compliance with the Small Business Regulatory Enforcement Fairness Act (SBREFA);
- A departmentwide effort to evaluate the economic effects of rules and regulations that are planned;
- Issuance of new guidance in the Departmental Manual to ensure the use of plain language in Government writing; and
- Encouragement of public outreach, including negotiated rulemaking.

We are committed to improving the regulatory process through the use of plain language. Simplifying regulations has resulted in a major rewrite of the regulations for onshore oil and gas leasing and operations in an easily understandable form that: (a) Puts previously published rules into one location in a logical sequence; (b) eliminates duplication by consolidating existing regulations and onshore orders and national notices to lessees; (c) incorporates industry standards by reference; and (d) implements performance standards in some of the operating regulations. Our regulatory process ensures that bureaus share ideas on how to reduce regulatory burden while meeting the requirements of the laws they enforce and improving their stewardship of the environment and resources under their purview.

Encouraging Responsible Management of the Nation's Resources

The Department's mission is to protect and provide access to our Nation's natural and cultural heritage and to honor our trust responsibilities to tribes. We are committed to this mission and to applying laws and regulations fairly and effectively. The Department's priorities are compliance, enforcement, prevention, solving problems, and protecting public health and safety. To this end, our bureaus encourage users of public resources to adopt long-term strategies designed to meet current needs while preserving resources for future generations.

An example of this is the ''no surprises'' policy of the U.S. Fish and Wildlife Service (FWS). This policy gives property owners an incentive to implement voluntary conservation measures for a proposed or candidate species, or a species likely to become a candidate or proposed in the near future. These property owners will receive assurances from FWS that additional conservation measures will not be required and additional land, water, or resource use restrictions will not be imposed should the species become listed in the future. This policy results in fewer fines, no ''surprises'' (in the form of unexpected fines) for conforming landowners, and better overall compliance with the Endangered Species Act.

Minimizing Regulatory Burdens

We are using the regulatory process to ease the burdens on various entities throughout the country. For instance, the Endangered Species Act (ESA) allows for the delisting of threatened and endangered species if they no longer need the protection of the ESA. We have identified approximately 40 species for which delisting or downlisting (reclassification from endangered to threatened) may be appropriate.

We use performance standards in a variety of regulations. These allow the affected entity to choose the most economical method to accomplish a goal provided it meets the requirements of the regulations. An example of this is Minerals Management Service's (MMS) training rule, which will allow companies with operations in the Outer Continental Shelf (OCS) to select their own training courses or programs for employees. The new rule will allow lessees and contractors to properly train the employees by any method they choose as long as the employees are competent. We anticipate that this will result in new and innovative training techniques and allow companies added flexibility in tailoring their training to employees' specific duties.

Encouraging Public Participation and Involvement in the Regulatory Procedure Process

Encouraging increased public participation in the regulatory process to make regulatory policies more responsive to our customers' needs is one of our top priorities. The Department is reaching out to communities to seek public input on a variety of regulatory issues. For example, every year FWS establishes migratory bird hunting seasons in partnership with ''flyway councils,'' which are made up of State fish and wildlife agencies. As the process evolves each year, FWS holds a series of public meetings to give other interested parties, including hunters and other groups, adequate opportunity to participate in establishing the upcoming season's regulations.

Similarly, the Bureau of Land Management (BLM) uses Resource Advisory Councils (RACs) made up of affected parties to help prepare regulations that it issues under the Rangeland Reform Act.

We encourage public consultation during the regulatory process. For example:

- OSM is continuing its outreach to interested groups to improve the substance and quality of rules and, to the greatest extent possible, achieve a consensus on regulatory issues.
- The Bureau of Indian Affairs is developing its roads program rule using the negotiated rulemaking process. Because of the importance of the roads program to the individual tribes and because of the varying needs of the tribal governments, the negotiated rulemaking process will result in a rule that better serves the diverse needs of the Native American community.
- The Bureau of Indian Affairs is also developing a rule in response to the Department's Trust Management Improvement Project–High Level Implementation Plan. The rule concerns grazing permits, leases on Indian lands, probate of Indian decedents' estates, and management of tribal and individual Indian money accounts held in trust. Tribal consultations were held prior to the development of the proposed rule and high-level consultations continue throughout Indian country during the ongoing comment period.
- The National Park Service is using the negotiated rulemaking process to revise the nonrecreation off-road driving regulations for Fire Island National Seashore. The existing regulations have evolved over a period of 35 years and have resulted in long-standing and serious controversy. NPS expects the negotiated rulemaking to produce regulations that will enjoy widespread public acceptance.

The Future of DOI

In compliance with the Government Performance and Results Act of 1993 (GPRA), we are preparing a comprehensive strategic plan to prepare DOI for the 21st century. The plan will cover the period from 2000 through 2005 and will be a stand-alone plan with five Departmental goals supported by the bureau goals. It gives employees and managers clear goals and strategies to help the Department meet its mission and fulfill its commitment to the nation. We believe that this plan must evolve in response to the changing natural and human environments. For this reason, our bureaus have already begun their strategic plans to respond to those changes and to prepare for others that may take place in the future.

A copy of DOI's current strategic plan (including updates that have been made during FY 2000) can be seen on our Web site at this address:

http://www.doi.gov/gpral

Bureaus and Offices Within DOI

The following brief descriptions summarize the regulatory functions of DOI's major regulatory bureaus and offices.

Office of the Secretary, Office of Environmental Policy and Compliance

The regulatory functions of the Office of Environmental Policy and Compliance (OEPC) stem from requirements under section 301(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA). Section 301(c) requires the development of natural resource damage assessment rules and the biennial review and revision, as appropriate, of these rules. Rules have been promulgated for the optional use of natural resource trustees to assess compensation for damages to natural resources caused by hazardous substances. OEPC is overseeing the study and possible promulgation of additional rules pursuant to section 301(c)(2) and the review and possible revision of the existing rules in compliance with section 301(c)(3).

In undertaking DOI's responsibilities under section 301(c), OEPC is striving to meet three regulatory objectives: (a) That the minimum amount of regulation necessary be developed; (b) that the assessment process provide for tailoring to specific discharges or releases; and (c) that the process not be considered punitive, but rather a system to achieve fair and just compensation for injuries sustained.

Bureau of Indian Affairs

The Bureau of Indian Affairs (BIA) is responsible for managing trust responsibilities to the Indian tribes and encouraging tribal governments to assume responsibility for BIA programs.

The Bureau's rulemaking and policy development processes are designed to foster public and tribal awareness of the standards and procedures that directly affect them. The processes also encourage the public and the tribes to participate in developing these standards and procedures. The goals of BIA regulatory policies are to: (a) Ensure consistent policies within BIA that result in dealing uniformly with the tribal governments; (b) facilitate tribal involvement in managing, planning, and evaluating BIA programs and services; and (c) ensure continued protection of tribal treaties and statutory rights.

Bureau of Land Management

The Bureau of Land Management manages about 264 million acres of land surface and about 570 million acres of Federal mineral estate. These lands consist of extensive grasslands, forests, mountains, arctic tundra, and deserts. Resources on the lands include energy and minerals, timber, forage, wild horse and burro populations, habitat for fish and wildlife, wilderness areas, and archeological and cultural sites. BLM manages these lands and resources for multiple use and the sustained yield of renewable resources. Primary statutes under which the Agency must operate include: The Federal Land Policy and Management Act of 1976; the General Mining Law of 1872; the Mineral Leasing Act of 1920, as amended; the Recreation and Public Purposes Act; the Taylor Grazing Act; and the Wild, Free-Roaming Horses and Burros Act.

The regulatory program mirrors statutory responsibilities and Agency objectives. Agency objectives include:

- Providing for a wide variety of public uses without compromising the long-term health and diversity of the land and without sacrificing significant natural, cultural, and historical resource values;
- Understanding the arid, semi-arid, arctic, and other ecosystems we manage and committing to using the best scientific and technical information to make resource management decisions;
- Understanding the needs of the public that use BLM-managed lands and providing them with quality service;
- Committing to recovering a fair return for using publicly owned resources and avoiding the creation of long-term liabilities for American taxpayers; and
- Resolving problems and implementing decisions in cooperation with other agencies, States, tribal governments, and the public.

The regulatory program contains its own objectives. These include preparing regulations that:

- Are the product of coordination and consultation with all affected members of the public;
- Are understandable to the general public, especially those to whom they are directly applicable; and
- Are reviewed periodically to determine whether or not BLM still needs them and whether or not they need to be updated to reflect statutory and policy changes.

Minerals Management Service

The Minerals Management Service (MMS) has two major responsibilities: (1) timely and accurate collection, distribution, accounting for, and auditing of revenues owed by holders of Federal onshore, offshore, and tribal land mineral leases in a manner that meets or exceeds Federal financial integrity requirements and recipient expectations, and (2) Management of the resources of the Outer Continental Shelf in a manner that provides for safety, protection of the environment, and conservation of natural resources. These responsibilities are carried out under the provisions of the Federal Oil and Gas Royalty Management Act, the Minerals Leasing Act, the Outer Continental Shelf Lands Act, the Indian Mineral Leasing Act, and other related statutes.

MMS's regulatory philosophy is to develop clear, enforceable rules that support the missions of its programs. MMS plans to issue final regulations to establish how it will offer deep water leasing incentives after expiration of the mandatory terms set by the Deep Water Royalty Relief Act (DWRRA) (Pub. L. 104-58) in 2001. In addition, current regulations at 30 CFR 203 give detailed instructions on how deep water leases issued *before* the DWRRA may apply and qualify for royalty-suspension on a case-by-case basis. MMS plans to revise and extend these instructions to certain additional categories of OCS leases, especially those issued *after* 2000. MMS will also continue to review rules and issue amendments in response to new technology and new industry practices.

MMS also plans to continue its review of existing regulations and to issue rules to refine the royalty management regulations in chapter II of 30 CFR. MMS's revisions to the royalty management regulations cover oil and gas valuation of Federal and Indian leases. In addition, the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 requires numerous changes to royalty management regulations.

Office of Surface Mining Reclamation and Enforcement

The Office of Surface Mining Reclamation and Enforcement (OSM) was created by the Surface Mining Control and Reclamation Act of 1977 (SMCRA) to ''strike a balance between protection of the environment and agricultural productivity and the Nation's need for coal as an essential source of energy.''

The principal regulatory provisions contained in title V of SMCRA set minimum requirements for obtaining a permit for surface coal mining operations, set standards for those operations, require land reclamation once mining ends, and require rules and enforcement procedures to ensure that the standards are met. Under SMCRA, OSM is the primary enforcer of SMCRA's provisions until the States achieve ''primacy''; that is, until they demonstrate that their regulatory programs meet all the specifications in SMCRA and have regulations consistent with those issued by OSM.

When a primacy State takes over the permitting, inspection, and enforcement activities of the Federal Government. OSM then changes its role from regulating mining activities directly to overseeing and evaluating State programs. Today, 24 of the 27 key coal-producing States have primacy. In return for assuming primacy, States are entitled to regulatory grants and to grants for reclaiming abandoned mine lands. In addition, under cooperative agreements, some primacy States have agreed to regulate mining on Federal lands within their borders. Thus, OSM regulates mining directly only in nonprimacy States, on Federal lands in States where no cooperative agreements are in effect, and on Indian lands.

SMCRA charges OSM with the responsibility of publishing rules as necessary to carry out the purposes of the Act. The fundamental mechanism for ensuring that the purposes of SMCRA are achieved is the basic policy and guidance established through OSM's permanent regulatory program and related rulemakings. This regulatory framework is developed, reviewed, and applied according to policy directives and legal requirements.

Litigation by the coal industry and environmental groups is responsible for some of the rules now being considered by OSM. Others are the result of efforts by OSM to address areas of concern that have arisen during the course of implementing OSM's regulatory program, and one is the result of legislation.

OSM has sought to develop an economical, safe, and environmentally sound program for the surface mining of coal by providing a stable and consistent regulatory framework. At the same time, however, OSM has recognized the need (a) to respond to local conditions, (b) to provide flexibility to react to technological change, (c) to be sensitive to geographic diversity, and (d) to eliminate burdensome recordkeeping and reporting requirements that over time have proved unnecessary to ensure an effective regulatory program.

Major regulatory objectives regarding the mining of surface coal include:

- Continuing outreach activities with interested groups during the rulemaking process to increase the quality of the rulemaking process, improve the substance of the rules, and, to the greatest extent possible, reflect consensus on regulatory issues;
- Minimizing the recordkeeping and regulatory compliance burden during rulemaking; and
- Publishing final rules to implement the Energy Policy Act of 1992, Public Law 102-486 and section 510(c) of SMCRA.

U.S. Fish and Wildlife Service

The U.S. Fish and Wildlife Service has three basic mission objectives:

- To develop and apply an environmental stewardship ethic based on ecological principles and scientific knowledge of fish and wildlife;
- To guide the conservation, development, and management of the Nation's fish and wildlife resources; and
- To administer a national program to provide the public with opportunities to understand, appreciate, and wisely use fish and wildlife resources.

These objectives are met through the following regulatory programs:

- Management of Service lands, primarily national wildlife refuges;
- Management of migratory bird resources;
- Conservation of certain marine mammals and endangered species;
- Allowance of certain activities that would otherwise be prohibited by law; and
- Administration of grant and assistance programs.

The Service maintains a comprehensive set of regulations in the first category—those that govern public access, use, and recreation on more than 500 national wildlife refuges and in national fish hatcheries. These uses are authorized only if they are compatible with the purpose for which each area was established, are consistent with State and local laws where practical, and afford the public appropriate economic and recreational opportunity. These regulations are developed and continually reviewed for improvements, with a substantial amount of public input, and are typically of limited geographical interest.

Management of migratory bird resources is covered by the second category of regulations, required by various international treaties. Annually, the Department issues a regulation on migratory bird hunting seasons and bag limits, developed in partnership with the States, American Indian tribal governments, and the Canadian Wildlife Service. Although issued annually, regulations such as these have been in existence for more than 50 years and have not significantly changed over that period of time. The regulations are necessary to permit migratory bird hunting that would otherwise be prohibited. Although recent declines in waterfowl populations have reduced the numbers of birds that may be harvested, the regulations generally do not change significantly from one year to another.

The third category includes regulations to fulfill the statutory obligation to identify and conserve species faced with extinction. The basis for determining endangered species is limited by law to biological considerations, although priorities for allocating Service resources are established consistent with the President's policies (by directing the Service's efforts to species most threatened and those whose protection is of the most benefit to the natural resource). Included in this program are regulations to enhance the conservation of listed species and of marine mammals for which DOI has management responsibility. This program also contains regulations that provide guidance to other Federal agencies to assist them in complying with section 7 of the Endangered Species Act, which requires them not to conduct activities that would jeopardize the existence of endangered species or adversely modify critical habitat of listed species. In designating critical habitat, the Service considers biological information and economic and other impacts of the designation. Areas may be excluded from the designation where the benefits of exclusion outweigh the benefits of inclusion, provided that the exclusion will not result in the extinction of the species.

The fourth category—the Service's regulatory program that permits activities otherwise prohibited by law—entails regulating possession, sale or trade, scientific research, and educational activities involving fish and wildlife and their parts or products. Generally, these regulations are supplemental to State protective regulations and cover activities that involve interstate or foreign commerce, which must comply with various laws and international obligations. The Service works continually with foreign and State governments, the affected industries and individuals, and other interested parties to minimize the burdens associated with Service-related activities. Easing these burdens through regulatory actions continues to balance possible benefits with adequate protection for the natural resource. Most of the regulatory activities are permissive in nature, and the concerns of the public generally center on technical issues.

The last category—the Service's assistance programs—includes a limited number of regulations necessary to ensure that assistance recipients comply with applicable laws and Office of Management and Budget (OMB) Circulars. Regulations in this program help the affected parties to obtain assistance and to comply with requirements imposed by Congress and OMB.

National Park Service

The National Park Service is dedicated to conserving the natural and cultural resources and values of the National Park System for the enjoyment, education, and inspiration of this and future generations. The Service is also responsible for managing a great variety

of national and international programs designed to help extend the benefits of natural and cultural resource conservation and outdoor recreation throughout this country and the world.

There are more than 375 units in the National Park System, including national parks and monuments; scenic parkways, preserves, trails, riverways, seashores, lakeshores, and recreation areas; and historic sites associated with important movements, events, and personalities of the American past.

The National Park Service develops and implements park management plans and staffs the areas under its administration. It relates the natural values and historical significance of these areas to the public through talks, tours, films, exhibits, and other interpretive media. It operates campgrounds and other visitor facilities and provides, usually through concessions, lodging, food, and transportation services in many areas. The National Park Service also administers the following programs: The State portion of the Land and Water Conservation Fund, Nationwide Outdoor Recreation coordination and information and State comprehensive outdoor recreation planning, planning and technical assistance for the National Wild and Scenic Rivers System, and the National Trails System, natural area programs, the National Register of Historic Places, national historic landmarks, historic preservation, technical preservation services, Historic American Buildings survey, Historic American Engineering Record, and interagency archeological services.

The National Park Service maintains regulations that help manage public use, access, and recreation in units of the National Park System. The Service provides visitor and resource protection to ensure public safety and prevent derogation of resources. The regulatory program develops and reviews regulations, maintaining consistency with State and local laws, to allow these uses only if they are compatible with the purpose for which each area was established.

Bureau of Reclamation

The Bureau of Reclamation's mission is to manage, develop, and protect water and related resources in an environmentally and economically sound manner in the interest of the American public. To accomplish this mission, Reclamation applies management, engineering, and scientific skills that result in effective and environmentally sensitive solutions.

Reclamation projects provide for some or all of the following concurrent purposes: Irrigation water service, municipal and industrial water supply, hydroelectric power generation, water quality improvement, groundwater management, fish and wildlife enhancement, outdoor recreation, flood control, navigation, river regulation and control, system optimization, and related uses.

Reclamation's regulatory program is designed to ensure that its mission is carried out expeditiously and efficiently.

DOI—Minerals Management Service (MMS)

PROPOSED RULE STAGE

65. OUTER CONTINENTAL SHELF OIL AND GAS LEASING-BIDDING SYSTEMS

Priority:

Other Significant

Legal Authority:

30 USC 181 et seq.; 30 USC 351 et seq.; 30 USC 1001 et seq.; 30 USC 1701 et seq.; 31 USC 3335; 43 USC 1301 et seq.; 43 USC 1331 et seq.; 43 USC 1337 et seq.; 43 USC 1801 et seq.

CFR Citation:

30 CFR 218; 30 CFR 256; 30 CFR 260

Legal Deadline:

None

Abstract:

This proposed rulemaking establishes the structure the Minerals Management Service (MMS) will use to offer deep water leasing incentives after expiration of the mandatory terms set by the Deep Water Royalty Relief Act (DWRRA) (Pub. L. 104-58) in 2001. This is also a plain English rewrite of the existing rules for bidding systems and joint bidding restrictions. Further, it extends rental obligations after a discovery for all leases issued after 2000.

Statement of Need:

Current deep water leasing incentives expire in November 2000. This rulemaking provides for an orderly transition from the generous incentives of the DWRRA to eventual elimination of incentives. Rather than the fixed royalty-suspension volumes set by the DWRRA, the rule establishes a flexible structure whereby MMS may change both water depths and royalty-suspension volumes periodically. This flexibility is vital because of the rapid change underway in the cost of deep water development. The extension of rental obligations responds to concerns with the U.S. Department of the Interior, Office of the Inspector General. (See Evaluation Report—Opportunity to Increase Offshore Oil and Gas Rental Revenues, Minerals Management Service, Report No. 99-I-387, March 1999.)

Summary of Legal Basis:

The primary legal basis for this rulemaking is the DWRRA, which defines the Secretary of the Interior's (1) authority to offer royalty suspension to promote development or increased production on producing and nonproducing leases, and (2) to encourage production of marginal resources on producing and nonproducing leases.

Alternatives:

We consider a range of alternatives such as (1) continue the same leasing incentive set by the DWRRA, (2) suddenly eliminate deep water leasing incentives or (3) codify new levels of leasing incentives in regulations. Because of technological progress and a better understanding of the deep water Gulf of Mexico (GOM), continuing the level of incentive set by the DWRRA would give an unneeded subsidy to new leases. Changing the current system under the second alternative would cause unnecessary disruption to a successful leasing policy. Despite record lease sales under the DWRRA, relatively few leases have been issued in ultra deep water areas of the GOM. Leasing incentives are still needed there. However, under option three, the program would be less flexible than necessary to accommodate changing market conditions. While the proposed rule does not commit MMS to specific water depths or royalty-suspension volumes, it does guarantee that a familiar and responsive structure will be implemented.

Anticipated Cost and Benefits:

We estimate compliance with this rulemaking would cost the oil industry approximately $35,000 annually over the next 5 years from extra rental payments after royalty-free production begins. Additional costs to industry and MMS would be negligible administrative expenses associated with notifying MMS when production starts. The benefits of this rulemaking would be estimated increases of 50 more tracts

sold per year; 15 more leases explored per year; and the eventual development of 10 to 20 more leases per year. These benefits are partially offset by reduced royalty collection in later years. However, because only a small percentage of tracts leased ultimately produce oil and gas, only a limited number of tracts receive a royalty suspension. Additional benefits would include simplification and increased certainty of royalty suspension, thereby raising bids per tract leased, and reduced dependence on field determinations and associated litigation.

Risks:

The risk of not modifying current oil valuation regulations is an abrupt decline in leasing and bids associated with termination of the deep water incentives program or pressure to continue the outdated, overly generous terms of the DWRRA.

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	
NPRM Comment Period End	11/00/00	
Proposed Notice of Sale No. 178	11/00/00	
Final Action	11/00/00	
Final Action Effective	12/00/00	
Final Notice of Sale No. 178	02/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Agency Contact:

Marshall B. Rose
Department of the Interior
Minerals Management Service
381 Elden Street
Herndon, VA 20170
Phone: 703 787-1536
Fax: 703 787-1141
Email: marshall.rose@mms.gov

RIN: 1010–AC69

DOI—MMS

66. DEEP WATER ROYALTY RELIEF FOR OUTER CONTINENTAL SHELF OIL AND GAS LEASES ISSUED AFTER 2000

Priority:

Other Significant

Legal Authority:

30 USC 181 et seq; 30 USC 1001 et seq; 30 USC 1701 et seq; 30 USC 351 et seq; 31 USC 9701; 43 USC 1301 et seq; 43 USC 1331 et seq; 43 USC 1801 et seq

CFR Citation:

30 CFR 203

Legal Deadline:

None

Abstract:

The rule explains who is eligible for relief, how they apply for relief, and the criteria they must meet to receive relief. The proposed rule makes a new class of leases, those sold after 2000 in the central and western Gulf of Mexico (GOM), eligible to apply for royalty suspensions to supplement any that may have been included in their original lease terms. Also, it updates certain requirements and authorizes royalty relief in special situations.

Statement of Need:

Because of the variation of geologic and economic circumstance, standard leasing terms do not encourage development of all potential reserves in the deep water GOM. The Deep Water Royalty Relief Act (DWRRA)(Pub. L. 104-58) authorized the Minerals Management Service (MMS) to promote development of marginal reserves. The existing regulations at 30 CFR 203 give detailed instructions on how deep water leases issued before the DWRRA may apply and qualify for royalty-suspension on a case-by-case basis. This proposed rule revises and extends these instructions to certain additional categories of OCS leases, especially those issued after 2000. Revisions to the existing instructions reflect experience with cases over the last 5 years. Also the proposed rule identifies circumstances when MMS may consider special royalty relief outside our established end-of-life and DWRR programs.

Summary of Legal Basis:

The OCS Lands Act is the basis for our regulations on suspending or lowering royalties on producing OCS leases. The DWRRA is the basis for regulations to reduce or eliminate royalty on non-producing leases in the GOM west of 87 degrees, 30 minutes West longitude. It gives the Secretary of the Interior this authority to (1) promote development or increased production on producing and non-producing leases or (2) encourage production of marginal resources on producing and non-producing leases.

Alternatives:

The specificity with which the current regulations were written was driven by the DWRRA to facilitate planning by potential applicants. Those regulations do not leave room for anything but a rulemaking fix. Otherwise, those new leases that legitimately need development assistance would be relegated to seeking relief under ad hoc special relief rules. Alternatively an extension of the DWRRA terms to fill a perceived gap may give future deep water lessees royalty-suspension terms that are not sufficiently responsive to current market conditions. Moreover, it is fairer to both applicants and taxpayers to establish clear and coherent rules by which individual leases can obtain the amount of royalty relief actually needed to induce development.

Anticipated Cost and Benefits:

This rule extends the benefit of discretionary royalty relief to certain OCS leases after November 2000 that qualify as marginally uneconomic. Lessees who choose to seek this discretionary royalty relief pay user fees that range from $12,000 to $49,000 per application, in addition to their internal costs of assembling the necessary data. Benefits from this rule come from production that otherwise would not occur or be deferred indefinitely. To date, one field qualifying for relief has gone into production and added 15 million barrels of oil equivalent to reserves in the GOM. Another on the verge of starting development would add 400 billion cubic feet of natural gas to reserves that otherwise would not be produced in the GOM.

Risks:

The risk of not modifying the discretionary royalty relief rule is that some marginal resources will be bypassed. Alternatively, royalty receipts could fall because overly generous relief will be given to many leases to avoid the loss in production by a few.

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	
NPRM Comment Period End	11/00/00	
Final Action	11/00/00	
Final Action Effective	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Agency Contact:

Marshall B. Rose
Department of the Interior
Minerals Management Service
381 Elden Street
Herndon, VA 20170
Phone: 703 787-1536
Fax: 703 787-1141
Email: marshall.rose@mms.gov

RIN: 1010–AC71

DOI—MMS

FINAL RULE STAGE

67. VALUATION OF OIL FROM INDIAN LEASES

Priority:

Other Significant

Legal Authority:

25 USC 2101 et seq; 25 USC 396 et seq; 30 USC 1001 et seq; 30 USC 1701 et seq; 30 USC 181 et seq; 30 USC 351 et seq; 25 USC 396a et seq

CFR Citation:

30 CFR 206

Legal Deadline:

None

Abstract:

This rule would modify the regulations that establish royalty value for oil produced from Indian leases and create a new form for collecting value and value differential data. These changes would decrease reliance on oil posted prices and make Indian oil royalty valuation more consistent with the terms of Indian leases.

Statement of Need:

Current oil valuation regulations rely primarily on posted prices and prices under arm's-length sales to value oil that is not sold at arm's-length. Over time, posted prices have become increasingly suspect as a fair measure of market value. This rulemaking would modify valuation regulations to place substantial reliance on the higher of crude oil spot prices, major portion prices, or gross proceeds, and eliminate any direct reliance on posted prices. This rulemaking would also add more certainty to valuation of oil produced from Indian leases.

Summary of Legal Basis:

The primary legal basis for this rulemaking is the Federal Oil and Gas Royalty Management Act of 1982, as amended, which defines the Secretary of the Interior's (1) authority to implement and maintain a royalty management system for oil and gas leases on Indian lands, and (2) trust responsibility to administer Indian oil and gas resources.

Alternatives:

We considered a range of valuation alternatives such as making minor adjustments to the current gross proceeds valuation method, using futures prices, using index-based prices with fixed adjustments for production from specific geographic zones, relying on some type of field pricing other than posted prices, and taking oil in-kind. We chose the higher of the average of the high daily applicable spot prices for the month, major portion prices in the field or area, or gross proceeds received by the lessee or its affiliate. We chose spot prices as one of the three value measures because (1) they represent actual trading activity in the market, (2) they mirror New York Mercantile Exchange futures prices, and (3) they permit use of an index price in proximity to the actual production whose value is being measured.

Anticipated Cost and Benefits:

We estimate compliance with this rulemaking would cost the oil and gas industry approximately $46,000 annually. Additional costs to industry and MMS would be up-front computer programming and other administrative costs associated with processing the new form. The benefits of this rulemaking would be an estimated $3.6 million increase in annual royalties collected on oil produced from Indian leases. Additional benefits would include simplification and increased certainty of oil pricing, reduced audit efforts, and reduced valuation determinations and associated litigation.

Risks:

The risk of not modifying current oil valuation regulations is that Indian recipients may not receive royalties based on the highest price paid or offered for the major portion of oil produced—a common requirement in most Indian leases. These modifications ensure that the Department fulfills its trust responsibilities for administering Indian oil and gas leases under governing mineral leasing laws, treaties, and lease terms.

Timetable:

Action	Date	FR Cite
ANPRM	12/20/95	60 FR 65610
ANPRM Comment Period End	03/19/96	
NPRM	02/12/98	63 FR 7089
NPRM Comment Period Extended	04/09/98	
NPRM Comment Period End	05/13/98	
Supplementary NPRM	01/05/00	65 FR 403
NPRM Comment Period Extended	02/28/00	
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Tribal

Agency Contact:

David S. Guzy
Chief Rules and Publications Staff
Department of the Interior
Minerals Management Service
MS 3021
P.O. Box 25165
Denver, CO 80225-0165
Phone: 303 231-3432
Fax: 303 231-3385
Email: david.guzy@mms.gov

RIN: 1010–AC24

DOI—Bureau of Land Management (BLM)

FINAL RULE STAGE

68. OIL AND GAS LEASING AND OPERATIONS

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

30 USC 181 et seq

CFR Citation:

43 CFR 3100 to 3160

Legal Deadline:

None

Abstract:

This rule will revise BLM's current Federal oil and gas leasing and operations regulations, except those concerning drainage (section 3100.2-2), combined hydrocarbon leasing (part 3140) and oil and gas leasing in the National Petroleum Reserve—Alaska (part 3130). The rule will: (1) Cite industry standards and incorporate them by reference rather than repeat those standards in the rule; (2) incorporate the requirements of the Onshore Oil and Gas Orders and national notices to lessees into the regulations to eliminate overlap with current regulations; (3) use performance standards in certain places instead of prescriptive requirements to allow more flexibility for operators and to protect the environment and Federal royalty interests; (4) increase certain bonding requirements; and (5) eliminate redundancies, clarify procedures and regulatory requirements and streamline procedures.

Statement of Need:

This rulemaking complies with the requirements of the Government Performance and Results Act, the recommendations of the National Performance Review, and other initiatives. It will be presented in a user-friendly format, presented by process rather than by subject matter.

Summary of Legal Basis:

The Mineral Leasing Act gives BLM the authority to issue and administer the terms of oil and gas leases on Federal lands, to conduct inspections of drilling operations and to promulgate and enforce regulations pertaining to oil and gas leasing and operations. BLM is the only Federal agency with authority to issue leases for publicly owned oil and gas resources.

Alternatives:

The only alternative to the proposed regulations would be to continue to operate under the existing regulations. These regulations are not performance-based and are at times ambiguous and hard to understand. Further, the important information found in Onshore Operating Orders is published separately from the regulations and at irregular intervals.

Anticipated Cost and Benefits:

BLM anticipates the following benefits: (1) More clearly written rules will be better understood by both oil and gas lessees and operators and members of the general public; (2) performance standards, rather than prescriptive requirements, will allow lessees and operators and BLM greater flexibility to deal with unique geological or engineering circumstances within the standards set by the rule; and (3) streamlining and clarifying procedures will result in better customer service and decreased time and money for both BLM and the user public.

Risks:

The public may misunderstand one or more performance standards. BLM will publish user guides that explain in detail the standards and will provide examples of how operators might meet specific standards.

Timetable:

Action	Date	FR Cite
NPRM	12/03/98	63 FR 66840
NPRM Comment Period End	07/19/99	
Final Action	10/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Local

Agency Contact:

Ian Senio
Regulatory Analyst
Department of the Interior
Bureau of Land Management
MS 401
Regulatory Management Team (WO-630)
1849 C Street NW.
Washington, DC 20240
Phone: 202 452-5049
Email: ian__senio@blm.gov

RIN: 1004–AC94

DOI—BLM

69. SURFACE MANAGEMENT (LOCATABLE MINERALS)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

18 USC 1001; 18 USC 3571 et seq; 30 USC 22; 30 USC 42; 30 USC 612; 43 USC 1061 et seq

CFR Citation:

43 CFR 3809

Legal Deadline:

None

Abstract:

The rule would improve the clarity and organization of the regulations, address technical advances in mining, incorporate policies BLM developed after we issued the previous regulations, reinstate certain financial guarantee provisions, and better protect natural resources and our Nation's natural heritage lands from the adverse impacts of mining.

Statement of Need:

This rulemaking reflects the Secretary of the Interior's judgment of the regulations required to prevent unnecessary or undue degredation of the public lands. Areas where the existing rules require upgrading include financial guarantees (to require financial guarantees for all operations greater than casual use, thereby ensuring the availability of resources for the completion of reclamation); enforcement (to implement section 302(c) of FLPMA and provide administrative enforcement tools and penalties); threshold for notice operations (to require plans of operations for operations more likely to pollute the land and those in sensitive areas); withdrawn areas (to require validity exams before allowing plans of operations to be approved in such areas); casual use (to clarify which activities do or do not constitute casual use); performance standards and the definition of unnecessary or undue degredation (to establish objective standards to reflect current mining technology); and others. Many of these shortcomings have been pointed out since 1986 in a series of congressional hearings, GAO reports, and DOI Inspector General reports.

Summary of Legal Basis:

This rulemaking is based on the Secretary of the Interior's non-delegable and independent responsiblility under FLPMA to take any action necessary to prevent unnecessary or undue degredation of the public lands, and a recognition that BLM's current rules may not be adequate to ensure this result. In enacting FLPMA, Congress intended that the Secretary determine what constitutes unnecessary or undue degredation and not that the States would do so on a State-by-State basis. Sections 302(b), 303(a), and 310 of FLPMA reflect this responsibility.

Alternatives:

In addition to the proposed rule, BLM is considering four alternatives. The first is to make no changes to the regulations. The second is to defer totally to the States for regulation of exploration and mining. The third is a maximum protection approach that would contain prescriptive design requirements. The fourth is to address only the six regulatory ''gaps'' identified by the National Research Council in a recent report.

Anticipated Cost and Benefits:

The Department has prepared a cost-benefit analysis. On balance the general public is expected to benefit by decreasing the public health and safety costs associated with the clean-up of hazardous and toxic substances generated by the mining of various locatable minerals (acid, draining, etc.). There may be slightly increased costs to operators on mining claims from their exploration, development, and reclamation activities, if the surface management regulations require using the best available technology in exploration, mining, and reclamation activities.

Risks:

Claimants unable to comply with increased mining costs could cease operations and go out of business. Some portion of the mining industry could cease exploration and mining operations in the United States and begin or increase mining operations in other countries whose policies are less stringent.

Timetable:

Action	Date	FR Cite
NPRM	02/09/99	64 FR 6422
NPRM Comment Period End	05/10/99	
Supplementary Proposed Rule	10/26/99	64 FR 57613
NPRM Comment Period End	02/23/00	
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local

Agency Contact:

Robert Anderson
Minerals Resources
Department of the Interior
Bureau of Land Management
Phone: 202 208-4201
Email: bob__m__anderson@blm.gov

RIN: 1004–AD22

BILLING CODE 4310–10–S

DEPARTMENT OF JUSTICE (DOJ)

Statement of Regulatory Priorities

The Department of Justice is not a major regulatory agency, and it carries out its vital investigative, prosecutorial, and other law enforcement activities principally through means other than the regulatory process. Even so, the Department does have significant responsibilities for implementing the Americans with Disabilities Act (ADA), as well as the immigration laws, including the Immigration Reform and Control Act of 1986 and the Immigration Act of 1990. The Department's key regulatory goals and initiatives are set forth in detail below.

The Department has worked actively to implement the general regulatory principles of Executive Order 12866. Relatively few of the Department's rules are significant regulatory actions requiring review by the Office of Management and Budget (OMB) under the Executive order. Accordingly, the orientation of the OMB review process to focus on significant rules has required the Department to increase its own efforts to ensure that all of its regulations are carefully reviewed for consistency with the Administration's regulatory principles, including the large majority of rules that are not reviewed directly by OMB as significant regulatory actions.

Pursuant to section 4(c) of Executive Order 12866, the Department of Justice provides the following statement of regulatory priorities, focusing in particular on three regulatory initiatives in the areas of civil rights and immigration.

In addition to the specific initiatives set forth below, several other components of the Department carry out important responsibilities through the regulatory process. Although their regulatory efforts are not singled out for specific attention in this regulatory plan, those components carry out key roles in implementing the Department's law enforcement priorities. In particular, the Drug Enforcement Administration (DEA) is responsible for controlling abuse of narcotics and dangerous drugs by restricting the aggregate supply of those drugs. DEA accomplishes its objectives through coordination with State, local, and other Federal officials in drug enforcement activities, development and maintenance of drug intelligence systems, regulation of legitimate controlled substances, and enforcement coordination and intelligence-gathering activities with foreign government agencies. DEA continues to develop and enhance regulatory controls relating to the diversion control requirements and to the requirements of the Comprehensive Methamphetamine Control Act of 1996, which regulates certain drug products that are being diverted for the production of methamphetamine. In addition, DEA has initiated an e-commerce study to identify the regulatory means under which legitimate handlers of controlled substances can use electronic technologies and signatures in the course of distributing and dispensing controlled substances.

Also, on March 20, 1997, the Federal Bureau of Investigation promulgated final cost recovery regulations under the Communications Assistance for Law Enforcement Act of 1994 (CALEA). Congress enacted CALEA to address the recent and continuing advances in telecommunications technology, which have impaired and, in some instances, precluded law enforcement agencies from fully conducting various types of court-authorized electronic surveillance. The Attorney General is authorized to reimburse carriers for all of the reasonable costs directly associated with the modifications they perform on equipment, facilities, and services deployed on or before January 1, 1995. These regulations provide the cost accounting standards for the reimbursements.

In response to public comments during the cost recovery rulemaking, the FBI published on April 20, 1998, a proposed rule defining the terms ''significant upgrade'' and ''major modification.'' The FBI plans to publish a supplemental notice of proposed rulemaking, which will define the terms replaced and significantly upgraded or otherwise undergone major modification.

On March 12, 1998, the FBI, on behalf of law enforcement, published a Final Notice of Capacity (following two previously published notices on the same subject) informing telecommunications carriers offering local exchange services and certain commercial mobile radio services (specifically cellular service and broadband PCS) of the estimated actual and maximum number of simultaneous interceptions that law enforcement might conduct on or after specified dates.

On December 18, 1998, the FBI published a Notice of Inquiry (NOI) soliciting information and suggestions from interested parties for developing reasonable capacity methodologies for characterizing the capacity requirements for telecommunications services other than those covered by the March 12, 1998, Final Notice of Capacity. The FBI issued a Further Notice of Inquiry (FNOI) on June 30, 2000. Information gathered in response to the FNOI will be used in the publication of an Initial Notice of Capacity for developing reasonable capacity methodologies for the paging, mobile satellite, specialized mobile radio, and enhanced specialized radio services.

Civil Rights

The Department and its Civil Rights Division are deeply committed to a rigorous and revitalized approach to the enforcement of this Nation's civil rights laws. In keeping with that commitment, the Division will be reviewing and updating its civil rights regulations implementing the Americans with Disabilities Act of 1990 (ADA).

The Department is planning to make revisions in its regulations implementing titles II and III of the ADA to amend the ADA Standards for Accessible Design (28 CFR part 36, appendix A) to be consistent with the revised ADA accessibility guidelines proposed by the U.S. Architectural and Transportation Barriers Compliance Board (Access Board) in November 1999. Title II of the ADA prohibits discrimination on the basis of disability by public entities, and title III prohibits such discrimination by places of public accommodation and requires accessible design and construction of places of public accommodation and commercial facilities. In implementing these provisions, the Department of Justice is required by statute to publish regulations that include design standards that are consistent with the guidelines developed by the Access Board.

The Access Board has been engaged in a multi-year effort to revise and amend its accessibility guidelines. The goals of this project have been: 1) to address issues such as unique State and local facilities (e.g., prisons, courthouses), recreation, play areas, and building elements specifically designed for children's use that were not addressed in the initial guidelines; 2) to promote greater consistency between the Federal accessibility requirements and the model codes; and 3) to provide greater consistency between the ADA guidelines and the guidelines that implement the Architectural Barriers Act. The Access Board has proposed and/or adopted guidelines that address all of these issues. Therefore, to comply

with the ADA requirement that the ADA standards remain consistent with the Access Board's guidelines, the Department will propose to adopt the changes previously proposed by the Access Board.

At the same time, the Department also plans to review its regulations implementing title II and title III (28 CFR parts 35 and 36) to ensure that the requirements applicable to new construction and alterations under title II are consistent with those applicable under title III, to review and update the regulations to reflect the current state of law, and to ensure the Department's compliance with applicable provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Immigration

The Immigration and Naturalization Service (INS) is responsible for facilitating the entry of persons legally admissible as visitors or as immigrants to the United States, for preventing unlawful entry or receipt of immigration benefits by those who are not entitled to receive them and for apprehending or removing those aliens who enter or remain illegally in the United States. Though many of the Administration's goals for more effective immigration process flow from either new statutory authority or increased resources, the regulatory process is a vital aspect of carrying out the goals of the immigration laws.

Certainly, one of the regulatory challenges facing the Department of Justice is to improve the effectiveness of those regulatory efforts. Commissioner Meissner established three fundamental goals at the time of her confirmation: To increase the professionalism of the Service, to provide immigration control with compassion, and to build the Service's role in immigration policy leadership and communication. The regulatory priorities for the Service follow those priorities, though other desired improvements may require legislative action. Two INS initiatives are included in this regulatory plan.

First, the Service will publish a proposed rule to implement the new grounds of inadmissibility and their waivers, especially those established under the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA). This regulation will clarify the interplay between the new grounds of inadmissibility and existing law and will set forth changes in procedures and policies. Second is the Service's ongoing effort to facilitate the U.S. business community's ability to comply with the employer sanctions provisions of the Immigration Control and Reform Act.

The Service anticipates additional progress in its efforts to simplify the employers' compliance with employment verification (Form I-9) requirements of the Act. The Service published a proposed rule on February 2, 1998. This proposal reflected numerous changes stemming from IIRIRA and from a comprehensive review of the 10-year-old verification regulations, as required by the Regulatory Flexibility Act. The result was a comprehensive overhaul of the regulations. The Service adopted a ''plain language'' approach and simplified the structure of the regulation. Both steps were well received by the public. In addition, the list of documents acceptable for employment verification was shortened, and several other requirements were clarified. The Service received thoughtful comments from the public on the proposal. Those are now being reviewed, and the Service anticipates publishing a final rule during the coming fiscal year.

DOJ—Civil Rights Division (CRT)

PROPOSED RULE STAGE

70. NONDISCRIMINATION ON THE BASIS OF DISABILITY IN STATE AND LOCAL GOVERNMENT SERVICES

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

5 USC 301; 28 USC 509, 510; 42 USC 12134; PL 101-336

CFR Citation:

28 CFR 35

Legal Deadline:

None

Abstract:

On July 26, 1991, the Department published its final rule implementing title II of the Americans with Disabilities Act (ADA). In late 1999, the U.S. Architectural and Transportation Barriers Compliance Board (Access Board) will issue its first comprehensive review of the ADA Accessibility Guidelines, which form the basis of the Department's ADA Standards for Accessible Design. The ADA (section 204(c)) requires the Department's standards to be consistent with the Access Board's guidelines. Therefore, the Civil Rights Division will publish a Notice of Proposed Rulemaking (NPRM) proposing to adopt the revisions proposed by the Access Board.

In addition to the statutory requirement for the rule, the social and economic realities faced by Americans with disabilities dictate the need for the rule. Individuals with disabilities cannot participate in the social and economic activities of the Nation without being able to access the programs and services of State and local governments. Further, amending the Department's ADA regulations will: Improve the format and usability of the ADA Standards for Accessible Design; harmonize the differences between the ADA standards and national consensus standards and model codes; update the ADA standards to reflect technological developments that meet the needs of persons with disabilities; and coordinate future ADA standards revisions with national standards and model code organizations. As a result, the overarching goal of improving access for persons with disabilities so that they can benefit from the goods, services, and activities provided to the public by covered entities will be met.

This rulemaking will also address changes to the ADA standards previously proposed in RIN 1190-AA26 and RIN 1190-AA38, which have been withdrawn. These changes will include technical specifications for facilities designed for use by children and accessibility standards for State and local government facilities that have previously been published by the Architectural and Transportation Barriers Compliance Board.

Statement of Need:

Section 504 of the ADA requires the Access Board to issue supplemental minimum guidelines and requirements for accessible design of buildings and facilities subject to the ADA, including titles II and III. Sections 204(c) and 306(c) of the ADA provide that the Attorney General shall promulgate regulations implementing titles II and III that are consistent with the Access Board's ADA guidelines. Because the Department of Justice is required by statute to promulgate regulations that do not go below the Access Board's minimum guidelines, and because this rule will adopt standards that are consistent with the guidelines issued by the Access Board, as also required

by statute, this rule is required by statute. Similarly, the Department's review of its title III regulation is being undertaken to comply with the requirements of the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Summary of Legal Basis:

The summary of the legal basis of authority for this regulation is set forth above in the Legal Authority and in the Statement of Need.

Alternatives:

The Department is required by the ADA to issue this regulation as described in the Statement of Need above. Pursuant to SBREFA, the Department's title III regulation will consider whether alternatives to the currently published requirements are appropriate.

Anticipated Cost and Benefits:

The Clinton Administration is deeply committed to ensuring that the goals of the ADA are met. Promulgating this amendment to the Department's ADA regulations will ensure that entities subject to the ADA will have one comprehensive regulation to follow. Currently,entities subject to title II of the ADA (State and local governments) have a choice between following the Department's ADA standards for title III, which were adopted for places of public accommodation and commercial facilities and which do not contain standards for common State and local government buildings (such as courthouses and prisons), or the Uniform Federal Accessibility Standards (UFAS). By developing one comprehensive standard, the Department will eliminate the confusion that arises when governments try to mesh two different standards. As a result, the overarching goal of improving access to the built environment to persons with disabilities will be better served.

The Access Board has analyzed the impact of applying its proposed amendments to ADAAG to entities covered by titles II and III of the ADA and has determined that they are a significant regulatory action for purposes of Executive Order 12866. The Access Board has prepared a regulatory assessment, which includes a cost impact analysis for certain accessibility elements and a discussion of the regulatory alternatives considered. The Access Board determined that its NPRM is an economically significant action. A summary of the Board's regulatory assessment is published at 64 FR 62282 (November 16, 1999). That assessment will also apply to the Department's proposed rule.

The Access Board's determination will apply as well to the revised ADA standards published by the Department. The Department's proposed procedural amendments will not have a significant impact on small entities.

The Access Board has made every effort to lessen the impact of its proposed guidelines on State and local governments but recognizes that the guidelines will have some federalism impacts. These impacts are discussed in the Access Board's Regulatory Assessment, which also applies to the Department's proposed rule.

Risks:

Without this amendment to the Department's ADA regulations, regulated entities will be subject to confusion and delay as they attempt to sort out the requirements of conflicting design standards. This amendment should eliminate the costs and risks associated with that process.

Timetable:

Action	Date	FR Cite
NPRM (RIN 1190-AA26)	06/20/94	59 FR 31808
NPRM (RIN 1190-AA26) Comment Period End	08/19/94	
RIN 1190-AA26 Merged Into 1190-AA46	02/15/00	65 FR 22968
Supplemental NPRM	12/00/00	
Supplemental NPRM Comment Period End	02/00/01	
Final Action	04/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

RIN 1190-AA46 is related to another rulemaking of the Civil Rights Division (RIN 1190-AA44), which will address changes to the ADA standards previously proposed in RINs 1190-AA26 and 1190-AA38. These latter two rulemakings have been withdrawn and merged into RINs 1190-AA44 and 1190-AA46. The changes to be made in RIN 1190-AA44 will include technical specifications for facilities designed for use by children and accessibility standards for State and local government facilities that have been previously been published by the Architectural and Transportation Barriers Compliance Board.

Agency Contact:

John L. Wodatch
Chief, Disability Rights Section
Department of Justice
Civil Rights Division
P.O. Box 66738
Washington, DC 20035-6738
Phone: 800 514-0301
TDD Phone: 800 514-0383
Fax: 202 307-1198

RIN: 1190–AA46

DOJ—Immigration and Naturalization Service (INS)

PROPOSED RULE STAGE

71. REVISED GROUNDS OF INADMISSIBILITY, WAIVERS FOR IMMIGRANTS AND NONIMMIGRANTS, AND EXCEPTIONS

Priority:

Other Significant. Major under 5 USC 801.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

5 USC 552; 8 USC 1158; 8 USC 1159; 8 USC 1160; 8 USC 1182; 8 USC 1183; 8 USC 1184; 5 USC 552a; 8 USC 1101; 8 USC 1102; 8 USC 1103; 8 USC 1151; 8 USC 1153; 8 USC 1154; 8 USC 1157

CFR Citation:

8 CFR 103; 8 CFR 207; 8 CFR 208; 8 CFR 209; 8 CFR 210; 8 CFR 212; 8 CFR 214; 8 CFR 232; 8 CFR 235; 8 CFR 240; 8 CFR 241; 8 CFR 245; 8 CFR 245a; 8 CFR 248; 8 CFR 249; 8 CFR 274a; 8 CFR 299; ...

Legal Deadline:

None

Abstract:

This regulation covers the grounds of inadmissibility applicable to those

aliens seeking admission to the United States temporarily or permanently. On September 30, 1996, the President signed the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), which substantially revised most grounds of inadmissibility under section 212 of the Act and the waivers available to both immigrants and nonimmigrants. The Immigration and Naturalization Service will publish regulations implementing these new grounds of inadmissibility and new/revised waiver provisions. In addition, this rule will incorporate the changes made to the grounds of inadmissibility and waivers provided for in the Immigration Act of 1990 (IMMACT 90), Public Law 101-649; the Miscellaneous and Technical Immigration and Naturalization Amendments of 1991 (MTINA), Public Law 102-232; the National Institutes of Health Revitalization Act of 1993, Public Law 103-43; the Immigration and Nationality Technical Corrections Act of 1991 (INTCA), Public Law 103-416; and the Anti-Terrorism and Effective Death Penalty Act of 1996 (AEDPA), Public Law 104-132, among others.

Statement of Need:

This regulation is necessary to implement the IIRIRA and IMMACT 90, Public Law 101-649; the MTINA, Public Law 102-232; the National Institutes of Health Revitalization Act of 1996, Public Law 103-43; and the AEDPA, Public Law 104-132.

Summary of Legal Basis:

See Statement of Need.

Alternatives:

None

Anticipated Cost and Benefits:

The INS anticipates a relatively low cost for staff time and resources necessary to conduct training and disseminate new guidelines to the field on implementation of the revised grounds of inadmissibility and waivers available to both immigrants and nonimmigrants. With respect to certain waivers for the new vaccination requirements that fall under the health-related grounds of inadmissibility, the blanket waiver procedures (that entail a delegation of authority from INS to Department of State consular officers) minimize the administrative burdens not only on the agencies responsible for administering this requirement—Centers for Disease Control, Department of State, and INS—but also the administrative burden on the alien applicant for such waiver. This, in turn, reduces the incentive for fraud that enhances the public health initiative contemplated by the newly enacted vaccination requirements. Moreover, the new application for waiver, Form I-724, that will be implemented concurrently with the promulgation of the regulation, will consolidate numerous forms currently used to determine eligibility for such classes of aliens.

Risks:

This regulatory initiative is critical for complete and clear implementation of the new grounds of inadmissibility and their waivers, especially those established under IIRIRA. The regulation will clarify the confusion that presently exists due to the interplay between the new grounds of inadmissibility and existing law. It will also clarify changes in procedures or policies.

Timetable:

Action	Date	FR Cite
NPRM-INS No. 1232 Comment Period End 2/5/90	01/05/90	55 FR 438
NPRM-INS No. 1413	04/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

Additional Information:

INS No. 1413-92

Consolidated INS Rules 1304, RIN 1115-AC01; 1235, RIN 1115-AB39; 1232, RIN 1115-AB45; and 1648, RIN 1115-AD62.

Agency Contact:

Sophia Cox
Staff Officer, Adjudications Division
Department of Justice
Immigration and Naturalization Service
Room 3214
425 I Street NW
Washington, DC 20536
Phone: 202 514-3228

RIN: 1115–AB45

DOJ—INS

FINAL RULE STAGE

72. REDUCTION OF THE NUMBER OF ACCEPTABLE DOCUMENTS AND OTHER CHANGES TO EMPLOYMENT VERIFICATION REQUIREMENTS (SECTION 610 REVIEW)

Priority:

Other Significant. Major under 5 USC 801.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

8 USC 1324a; PL 104-208

CFR Citation:

8 CFR 274a

Legal Deadline:

Final, Statutory, March 31, 1998, An interim rule, published September 30, 1997, makes the minimal changes required by statute. The provisions will remain in effect until completion of this rulemaking.

Abstract:

On September 30, 1996, the President signed the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA). Section 412(a) of IIRIRA requires a reduction in the number of documents that may be accepted in the employment verification process. Section 412(d) clarifies the applicability of section 274A to the Federal Government. Section 610 of the Regulatory Flexibility Act requires agencies to review rules that have a significant economic impact on a substantial number of small entities every 10 years. The Service is conducting this review in conjunction with IIRIRA implementation. The proposed rulemaking published 2/12/98 implements sections 212(a) and (d) of IIRIRA and proposes other changes to the employment verification process identified through that review. A revised Form I-9 was included with the proposed rulemaking.

The comment period closed on 4/3/98. The Service is analyzing the comments and taking into consideration issues raised by the Alien Registration (MD) (I-551) program amending 10/1/99. It should be noted that this action

supersedes the previously published regulatory plan titled ''Reduction in the Number of Documents Accepted for Employment Verification.'' In order to avoid confusion, this regulatory action is being referenced under the current RIN, which captures all prior actions related to employment verification.

INS No. 1947-98, Interim Rule published 2/9/99 (64 FR 6187). The ''Receipt Rule'' permits employees to present their employer certain types of ''receipts'' in lieu of a document listed on the Form I-9. (Previously under RIN 1115-AE94, which was withdrawn and placed under AB73 due to the relationship of the regulations.)

Statement of Need:

The Immigration Reform and Control Act of 1986 amended the Immigration and Nationality Act (INA) to require employers to hire only persons who are eligible to work in the United States and to verify the work eligibility of all new hires. Form I-9 was designated for that purpose. Newly hired individuals must attest to the status that makes them eligible to work and present documents that establish their identity and eligibility to work. In its third review of employer sanctions regulations, the GAO reported that employer confusion over the ''multiplicity'' of acceptable documents contributed to discrimination against authorized workers. See GAO/GGD Report No. 90-62, dated March 29, 1990. Section 412(a) of IIRIRA requires a reduction in the number of documents that may be accepted in the employment verification process. Implementation of these provisions, along with other simplifications and clarifications, will reduce potential employment discrimination based upon misapplication of the verification requirements.

Summary of Legal Basis:

The legal basis of authority for this regulation is set forth above in Legal Authority. Parts of this regulatory action are required by IIRIRA.

Alternatives:

The lists of documents for employment verification have been controversial throughout the 10 years that employer sanctions have been in effect. When the INS first published implementing regulations in 1987, the supplementary information noted that the list of identity documents had been expanded in response to public comment. When the law was new, a consensus emerged that an inclusive list of documents would ensure that all persons who are eligible to work could easily meet the requirements. As early as 1990, there was evidence that some employers found the list confusing. As noted in the ''Statement of Need,'' GAO linked employer confusion over the ''multiplicity'' of acceptable documents to discrimination against authorized workers. The INS has taken steps to address this criticism. In July 1988, INS committed to the establishment of a uniform employment authorization policy. First the INS limited the number and types of ''paper'' documents on which employment could be authorized. Second, a standardized Employment Authorization Document (EAD) I-688B was introduced in 1989. In February 1997, a more secure EAD Form (I-766) was produced with state of the art technology.

Anticipated Cost and Benefits:

Employment is often the magnet that attracts individuals to come to or stay in the United States illegally. The employer sanctions provisions help reduce the strength of this magnet by requiring employers to hire only those individuals who may legally work in the United States. This rule, by reducing the number of documents that are acceptable for employment eligibility verification purposes and clarifying other requirements, will reduce confusion on the part of employers. This, in turn, will increase employer compliance, preserving jobs for persons who are eligible to work in the United States.

Risks:

An employment eligibility verification system that relies on a wide range of documents may result in employment discrimination based upon misapplication of the employment eligibility verification requirements. In addition, a complicated system may encourage fraud and result in individuals who are authorized to work in the United States being displaced by unauthorized individuals.

Timetable:

Action	Date	FR Cite
NPRM-INS No. 1399 Comment Period End 12/23/93	11/23/93	58 FR 61846
NPRM-INS No. 1339S Comment Period End 07/24/95	06/22/95	60 FR 32472
Notice-INS No. 1713 INS No. 1713 Applications Due 01/29/96	11/30/95	60 FR 61630
Appl. Extension Through 3/8/96 Notice Pilot Demonstration Program-INS No. 1713	02/06/96	61 FR 4378
Final Rule-INS No. 1399E	09/04/96	61 FR 46534
Interim Final Rule INS No. 1818	09/30/97	62 FR 51001
NPRM-INS No. 1890-97 Comment Period End 04/03/98	02/02/98	63 FR 5287
Final Rule INS No. 1890-97	04/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

The deadline for implementing section 412(a) of IIRIRA was extended to March 31, 1998, by Public Law 105-54. This rulemaking has been delayed by the need to coordinate implementation with other provisions of IIRIRA, by several complex policy and regulatory issues that have taken time to resolve, and by the review required by section 610 of the Regulatory Flexibility Act.

INS No. 1890-97; PL 104-208, title 4.

INS Nos. 1399 and 1399S-94, Control of Employment of Aliens, Supplemental Rule; Action for INS No. 1399 and 1399S is canceled as a result of IIRIRA requirements.

INS No. 1399E is an extracted portion of INS No. 1399, published separately to allow for the production of a new, more secure Employment Authorization Document.

INS No. 1713-95, Demonstration Project for Electronic I-9s, contact Bob Reed, (202) 514-2998.

Interim Rule INS No. 1818 was published on 9/30/97 at 62 FR 51001 to maintain the status quo as much as possible until the Service completes the more comprehensive document reduction initiative designated by INS No. 1890-97.

Agency Contact:

Linda Dodd-Major
Director, Business Liaison Branch,
Adjudications Division
Department of Justice
Immigration and Naturalization Service
425 I Street NW
Washington, DC 20536
Phone: 202 305-2529
Fax: 202 305-2523
Email: linda.dodd-major@usdoj.gov

RIN: 1115–AB73

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DEPARTMENT OF LABOR (DOL)

2000 Regulatory Plan

Executive Summary

The Secretary of Labor has set three strategic goals for the Department of Labor (DOL): first, to enhance opportunities for America's workforce; second, to promote the economic security of workers and their families; and third, to foster quality workplaces that are safe, healthy, and fair. The 180 labor laws and related regulations that DOL administers advance these goals.

Regulations that implement newly enacted legislation help DOL and its stakeholders work together to achieve that statute's goal by providing clear, effective, flexible plans of action. Updating existing regulations promotes DOL's goals by removing ineffective standards and making old rules easier to understand and use. DOL has always recognized that changes in the workplace, such as new business practices, improved or safer technologies, or new hazards, can make existing rules ineffective or demand the creation of new ones.

In keeping with the President's Plain Language Memorandum of June 1, 1998, the Department remains committed to issuing regulations that are both easy to understand and effective and that minimize burdens on the regulated community. Regulations that are easy to understand promote voluntary compliance and improve customer satisfaction. Most employers comply with workplace regulations if given the information they need. When writing or revising rules, DOL will also explore new approaches that would achieve our regulatory goals at lower costs and with greater flexibility for the regulated community. DOL's policy is to ensure that those who are protected by the new rules or must abide by them are given the opportunity to participate in the rulemaking process and are provided timely, user-friendly compliance assistance materials.

DOL's 2000 Regulatory Plan highlights the Department's 20 most important, significant regulations from five of our agencies: Employment Standards Administration (ESA), Employment and Training Administration (ETA), Mine Safety and Health Administration (MSHA), Occupational Safety and Health Administration (OSHA), and Pension and Welfare Benefits Administration (PWBA). The entries in the Regulatory Plan were carefully selected as the most important; that is, they are essential to the fulfillment of the Department's three strategic goals.

The Secretary of Labor's Strategic Goals

A Prepared Workforce: This first goal is to assure that American workers have the opportunity to obtain the information and tools they will need throughout their careers to enhance their productivity and raise their standard of living. The new economy requires workers to continue their education beyond a high school diploma, or even a college degree — education must mean lifelong learning and ongoing skill development.

Secure Workforce: The rapidly changing global economy imposes economic security concerns on both employers and employees. The life cycles of many products are shorter and shorter, requiring quick adjustments by both industry and labor. Competitive forces can lead to plant closures and layoffs, plant and employee relocations, and in some cases, to attempts to avoid legal obligations. The Department will continue to do all it can to increase compliance with worker protection laws, protect worker benefits, and provide worker retraining.

Quality Workplaces: The intensely competitive global economy offers unparalleled opportunities for both business and labor, but also can pressure some employers to ignore their responsibilities to their employees. Smart employers recognize that they must utilize all of the talent that is available to them and that a quality workplace is a productive workplace. The Department works with employers to prevent workplace discrimination and to help them recognize the benefits of ensuring equal opportunity and equal pay for all workers. DOL also is committed to doing all it can to guarantee safety and health in the workplace and to obtain compliance with other important labor standards such as the minimum wage, overtime, child labor rules, and family and medical leave requirements. Safe and healthful workplaces not only benefit employees, but also benefit employers. Fewer accidents and injuries result in less downtime as well as lower workers' compensation costs. The Department's ultimate goal is full compliance with employment laws which will ensure workers a safe, healthy, and fair workplace.

The Department's Regulatory Priorities

Section 5001 of the Balanced Budget Act of 1997 authorized the Department of Labor to provide Welfare-to-Work Grants to State and local communities to create additional job opportunities for the hardest-to-employ recipients of the Temporary Assistance for Needy Families (TANF) — the new system of block grants created by the welfare reform legislation. The Employment and Training Administration (ETA) has issued interim final regulations and other guidance under this legislation. Moving people from welfare to work is not only a primary goal of Federal welfare to work opportunities, but also responds to the Secretary's goal of a Prepared Workforce. Guidance and regulations reflect minimal amplification of the law, and were written only when further information or clarification was needed to make the program operational. Reporting requirements assure program integrity and provide timely information for tracking performance against established measures. Performance measures will be consistent with long-term goals. Wherever possible, existing regulations and systems will be used. ETA will issue a final rule based on the comments received on the November 18, 1997 Interim Final Rule. A new Interim Final Rule will be issued for comment at the same time based on the Welfare-to-Work and Child Support Amendments that were enacted in November 1999.

The Pension and Welfare Benefits Administration (PWBA) administers and enforces the provisions of the Employee Retirement Income Security Act, as amended (ERISA). ERISA establishes reporting, disclosure and other standards applicable to an estimated 700,000 private-sector employee pension benefit plans, covering approximately 92 million participants and an estimated 2.5 million group health benefit plans covering 131 million participants and dependents, and 3.4 million other welfare benefit plans covering approximately 190 million participants.

PWBA's regulatory priorities continue to focus on efforts to simplify and otherwise facilitate compliance with benefit laws, to improve pension and welfare plan coverage, and to protect the benefits of American workers. PWBA's top regulatory priorities involve implementation of enhanced standards for group health plans, including strengthening the claims review processes and improving the disclosure of health care benefit information. PWBA also will continue to work with the Department of Health and Human Services, the Department of Treasury,

and the Internal Revenue Service to issue final regulatory guidance under the Health Insurance Portability and Accountability Act.

The Employment Standards Administration's (ESA's) Wage and Hour Division enforces several statutes establishing minimum labor standards that protect the Nation's work force, including the Fair Labor Standards Act (FLSA), the Migrant and Seasonal Agricultural Worker Protection Act, the Family and Medical Leave Act, the Service Contract Act, the Davis-Bacon Act, the Employee Polygraph Protection Act, and certain provisions of the Immigration and Nationality Act. These labor standards include requirements for payment of minimum wages and overtime pay, protections for working youth under child labor standards, job protection for employees who take leave for certain family or medical reasons, and minimum working conditions for agricultural workers. The regulatory activities required to implement these statutory responsibilities represent an important aspect of the Division's work — affecting over 100 million employees in the work force. When developing regulatory proposals, the Division's focus is to assure fair, safe and healthful workplaces for the Nation's workers, while at the same time providing clear compliance guidance and minimizing burdens on the regulated community.

Updating the child labor regulations issued under the FLSA will help guarantee a safe, healthy, and fair workplace for the Nation's working youth and help them balance their education with job-related experiences. Many workers first gain job-related skills through their exposure to work as teenagers. Updated child labor regulations that better reflect today's workplace will assist young workers in having safe jobs and enhance their opportunity to gain the skills to find and hold good jobs. Ensuring safe and reasonable work hours for working youth will also ensure that top priority is given to education.

Updating and clarifying the criteria that define the minimum wage and overtime exemptions for executive, administrative, professional, and outside sales employees under the FLSA, and clarifying when helpers may be used on federally funded and assisted construction contracts covered by the prevailing wage requirements of the Davis-Bacon and related acts, will help guarantee workers a secure and quality workplace. Revising and updating these regulations will help employers meet their obligations voluntarily and enhance employees' understanding of their rights and benefits.

ESA's Office of Federal Contract Compliance Programs (OFCCP) is charged with enforcing the requirements of Executive Order 11246, selected provisions of the Vietnam Era Veterans' Readjustment Assistance Act of 1974 (VEVRAA), and Section 503 of the Rehabilitation Act of 1973. Regulations issued under the Executive Order and the two acts cover nondiscrimination and affirmative action obligations for federal contractors and subcontractors. They help to ensure that workplace policies and practices are fair and provide equal opportunity to all workers. OFCCP's regulatory plan entry, the proposed amendments to regulations implementing Executive Order 11246, some of which became effective in 1997, will streamline and clarify the existing regulatory language and reduce paperwork requirements of covered Federal contractors while ensuring that their obligations under the Executive Order and the two acts are met. This final rule encourages contractors to analyze their own compensation and other employment practices to ensure that all employees are fairly treated. In addition, this plan entry will help fulfill the Administration's Equal Pay and Civil Rights initiative to eliminate wage discrimination by identifying and remedying compensation discrimination by Federal contractors.

The mission of the Mine Safety and Health Administration (MSHA) is to protect the safety and health of the nation's miners. The Federal Mine Safety and Health Act of 1977 (Mine Act) places primary responsibility for preventing unsafe and unhealthy working conditions in mines on the operators, with the assistance of miners. The Mine Act requires MSHA to determine compliance with Federal safety and health standards through inspections and investigations, and to work cooperatively with States and the mining industry to improve training programs aimed at preventing accidents and occupationally caused diseases.

MSHA is committed to providing the nation's miners a safer and healthier workplace. Despite MSHA past efforts, miners face safety and health hazards daily at levels unknown in most other occupations. Government intervention alone cannot eliminate occupational deaths, injuries, and illnesses in mining. The commitment of miners, mine operators and government is needed. MSHA's Regulatory Plan reflects this commitment. It will continue to concentrate on improving existing health standards and addressing emerging health hazards in mining.

Several significant regulatory actions exemplify MSHA's commitment to improving workplace health for miners. MSHA intends to issue final rules for diesel particulate matter in underground coal and metal and nonmetal mines to reduce the potential health hazards associated with the exhaust emitted by diesel-powered equipment. Those hazards range from headaches and nausea to respiratory disease and cancer.

While there have been significant reductions in levels of respirable coal mine dust over the years, some miners exposed to respirable coal mine dust at certain mine operations continue to develop coal workers' pneumoconiosis. MSHA intends to issue final rules to provide a means to verify operators' coal dust control plans and to prevent overexposure to respirable coal mine dust on each and every working shift. MSHA has also proposed that the Agency take over the operator coal mine dust sampling program.

MSHA has identified the above actions for the October 2000 Regulatory Plan because occupational lung disease is the most serious and pervasive occupational illness in mining. MSHA believes these combined initiatives will greatly improve health protection for miners and, therefore, they are tied directly and significantly to the Agency's mission and strategic plan.

Several years ago, the Occupational Safety and Health Administration (OSHA) recognized the need to find a better way to carry out its mission — to save the lives and improve the safety and health of America's working men and women. In the regulatory arena, this meant that OSHA had to change its regulatory approach to establish clear and sensible priorities, emphasize consensus-based approaches to rulemaking, and focus on developing an ergonomics rule.

The seven rules in OSHA's Regulatory Plan directly support OSHA's mission as well as the Secretary's goal for assuring America's workers a quality workplace. Each rule is designed to reduce occupational deaths, injuries, and illnesses among America's workers or to simplify OSHA recordkeeping requirements for employers. OSHA's Plan entries address the causes of the most dangerous occupational injuries, i.e., those with fatal or disabling consequences, those affecting a large

number of workers, those for which recognized solutions are available, or those identified as the top priorities by the Agency's Strategic Planning process.

Some of OSHA's standards, particularly those adopted wholesale from national consensus standards in 1971, are written in highly detailed, specification-driven language that limits compliance flexibility. To address this problem, OSHA has launched a series of initiatives aimed at streamlining and rationalizing the Agency's regulations and ensuring that all future OSHA rules will pass plain language and common sense tests. In addition, the Agency is actively soliciting input from stakeholders — business, labor, small employers, professional associations, and affected government entities — as it moves forward on these rule initiatives. The OSHA rules in the Regulatory Plan reflect the rulemaking approach that is being followed by the New OSHA. For example, the Agency is involving stakeholders throughout the development of its rules. In 1999 and 2000, OSHA held several meetings with stakeholders interested in the forthcoming silica standard and the electric power transmission and distribution standard for the construction industry.

One of the most important regulatory initiatives ever undertaken by OSHA — development of an ergonomics program rule — is the centerpiece of the Agency's current Regulatory Plan. This rule will ensure that employers in general industry whose employees experience a work-related musculoskeletal disorder (MSD) implement ergonomics programs. Evidence of the effectiveness of ergonomics programs in achieving OSHA's ultimate goal — the prevention of musculoskeletal disorders on the job — is widespread and growing daily, as more and more companies report that their accident rates and their workers' compensation costs have fallen after the implementation of such programs. OSHA proposed an ergonomics program standard in November 1999. The Agency then held nine weeks of public hearings, at which more than 500 witnesses testified. The Agency is reviewing the extensive record for this rulemaking at the present time. If the evidence in the record supports a final rule, OSHA plans to issue one late in 2000.

The Department believes that, by actively involving both employers and employees in the implementation of ergonomics programs, this standard will help to produce the high-performance workplace of tomorrow. In sum, OSHA's regulatory strategy is designed to achieve a body of standards that will make sense to ordinary people, protect the safety and health of the U.S. workforce, and enhance the productivity of American businesses.

DOL—Employment Standards Administration (ESA)

PROPOSED RULE STAGE

73. DEFINING AND DELIMITING THE TERM ''ANY EMPLOYEE EMPLOYED IN A BONA FIDE EXECUTIVE, ADMINISTRATIVE, OR PROFESSIONAL CAPACITY'' (ESA/W-H)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal goverments and the private sector.

Legal Authority:

29 USC 213(a)(1)

CFR Citation:

29 CFR 541

Legal Deadline:

None

Abstract:

These regulations set forth the criteria for exemption from the Fair Labor Standards Act's minimum wage and overtime requirements for ''executive,'' ''administrative,'' ''professional'' and ''outside sales employees.'' To be exempt, employees must meet certain tests relating to duties and responsibilities and be paid on a salary basis at specified levels. A final rule increasing the salary test levels was published on January 13, 1981 (46 FR 3010), to become effective on February 13, 1981, but was indefinitely stayed on February 12, 1981 (46 FR 11972). On March 27, 1981, a proposal to suspend the final rule indefinitely was published (46 FR 18998), with comments due by April 28, 1981. As a result of numerous comments and petitions from industry groups on the duties and responsibilities tests, and as a result of case law developments, the Department concluded that a more comprehensive review of these regulations was needed. An ANPRM reopening the comment period and broadening the scope of review to include all aspects of the regulations was published on November 19, 1985, with the comment period subsequently extended to March 22, 1986.

The Department has revised these regulations since the ANPRM to address specific issues. In 1991, as the result of an amendment to the Fair Labor Standards Act (FLSA), the regulations were revised to permit certain computer systems analysts, computer programmers, software engineers, and other similarly skilled professional employees to qualify for the exemption, including those paid on an hourly basis if their rates of pay exceed 6 1/2 times the applicable minimum wage. Also, in 1992 the Department issued a final rule which modified the exemption's requirement for payment on a ''salary basis'' for otherwise exempt public sector employees.

Statement of Need:

These regulations contain the criteria used to determine if an employee is exempt from the FLSA as an ''executive,'' ''administrative,'' ''professional,'' or ''outside sales'' employee. The existing salary test levels used in determining which employees qualify as exempt were adopted in 1975 on an interim basis. These salary level tests are outdated and offer little practical guidance in applying the exemption. In addition, numerous comments and petitions have been received from industry groups regarding the duties and responsibilities tests in the regulations, requesting a review of these regulations.

These regulations have been revised to deal with specific issues. In 1991, as the result of an amendment to the FLSA, the regulations were revised to permit certain computer systems analysts, computer programmers, software engineers, and other similarly skilled professional employees to qualify for the exemption, including those paid on an hourly basis if their rates of pay exceed 6 1/2 times the applicable minimum wage. Also in 1991, the Department undertook separate rulemaking on another aspect of the regulations, the definition of ''salary basis'' for public-sector employees. Because of the limited nature of these revisions, the regulations are still in need of updating and clarification.

Summary of Legal Basis:

These regulations are issued under the statutory exemption from minimum wage and overtime pay provided by section 13(a)(1) of the Fair Labor Standards Act, 29 USC 213(a)(1), which requires the Secretary of Labor to issue regulations that define and delimit the terms ''any employee employed in a bona fide, executive, administrative, or professional capacity ..., or in the capacity of outside salesman...,'' for purposes of applying the exemption to employees who meet the specified criteria.

Alternatives:

The Department will involve affected interest groups in developing regulatory alternatives. Following completion of these outreach and consultation activities, full regulatory alternatives will be developed.

Although legislative proposals have been introduced in Congress to address certain aspects of these regulations, the Department continues to believe revisions to the regulations are the appropriate response to the concerns raised. Alternatives likely to be considered range from particular changes to address ''salary basis'' and salary level issues to a comprehensive overhaul of the regulations that also addresses the duties and responsibilities tests.

Anticipated Cost and Benefits:

Some 32 million employees are estimated to be within the scope of these regulations. Legal developments in court cases are changing the guiding interpretations under this exemption and creating law without considering a comprehensive analytical approach to current compensation concepts and workplace practices. Clear, comprehensive, and up-to-date regulations would provide for central, uniform control over the application of these regulations and ameliorate many concerns. In the public sector, State and local government employers contend that the rules are based on production workplace environments from the 1940s and 1950s that do not readily adapt to contemporary government functions. The Federal Government also has concerns regarding the manner in which the courts and arbitration decisions are applying the exemption to the Federal workforce. Resolution of confusion over how the regulations are to be applied in the public sector will ensure that employees are protected, that employers are able to comply with their responsibilities under the law, and that the regulations are enforceable. Preliminary estimates of the specific costs and benefits of this regulatory action will be developed once the various regulatory alternatives are identified.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
Indefinite Stay of Final Rule	02/12/81	46 FR 11972
Proposal To Suspend Rule Indefinitely	03/27/81	46 FR 18998
ANPRM	11/19/85	50 FR 47696
Extension of ANPRM Comment Period From 01/21/86 to 03/22/86	01/17/86	51 FR 2525
ANPRM Comment Period End	03/22/86	51 FR 2525
NPRM	09/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Local, State, Federal

Federalism:

Undetermined

Agency Contact:

John R. Fraser
Deputy Administrator (WHD)
Department of Labor
Employment Standards Administration
Room S3502
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-0051
Fax: 202 693-1432

RIN: 1215–AA14

DOL—ESA

FINAL RULE STAGE

74. GOVERNMENT CONTRACTORS: NONDISCRIMINATION AND AFFIRMATIVE ACTION OBLIGATIONS, EXECUTIVE ORDER 11246 (ESA/OFCCP)

Priority:

Economically Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

EO 11246, as amended

CFR Citation:

41 CFR 60-1; 41 CFR 60-2

Legal Deadline:

None

Abstract:

These regulations cover nondiscrimination and affirmative action obligations of Federal contractors under Executive Order (E.O.) 11246 as amended. The part 60-1 final rule, published 8/19/97, revised portions of the regulations implementing E.O. 11246. OFCCP's review of regulatory options continues with emphasis on streamlining and clarifying the regulatory language and reducing paperwork requirements associated with compliance. OFCCP plans to issue revisions to written affirmative action program (AAP) requirements to reduce burdens on the regulated community and to improve the enforcement of the Executive order.

Statement of Need:

Portions of the regulations implementing E.O. 11246 need to be revised to reflect changes in the law that have occurred over time, and other portions need to be streamlined and clarified. E.O. 11246 requires all Federal contractors and subcontractors and federally assisted construction contractors and subcontractors to apply a policy of nondiscrimination and affirmative action in employment with respect to race, color, religion, sex, and national origin. The regulatory revisions are necessary in order to allow the DOL to effectively and efficiently enforce the provisions of the Executive order. As a first step in updating its Executive order regulations, the Department published changes to the provisions that govern preaward review requirements; recordkeeping and record retention requirements; certification requirements; and related provisions. In addition, other revisions have been made that conform E.O. 11246 regulations to the recent changes made in the Department's regulations implementing section 503 of the Rehabilitation Act.

A second phase of revision will change provisions that govern requirements for written affirmative action plans and the provisions concerning evaluation of contractor procedures.

Summary of Legal Basis:

No aspect of this action is required by statute or court order.

Alternatives:

After careful review, it was decided that the most effective way to improve compliance with the E.O. 11246 provisions and reduce burdens on contractors was to revise these regulations. Administrative actions alone could not produce the desired results.

Anticipated Cost and Benefits:

It is anticipated that the net effect of the changes will increase compliance with the nondiscrimination and affirmative action requirements of the Executive Order and reduce compliance costs to Federal contractors. The Department will also be able to utilize its resources more efficiently and more effectively.

Risks:

Failure to move forward with OFCCP's regulatory agenda could cause the continuation of outdated methods of evaluating contractor compliance and impede effective enforcement of E.O. 11246.

Timetable:

Action	Date	FR Cite
NPRM Affirmative Action Plans (60-2)	05/04/00	65 FR 26088
NPRM Comment Period End	07/03/00	
Final Rule	12/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Undetermined

Additional Information:

Under the Reinventing Government initiative, OFCCP's emphasis is on regulatory reform, e.g., to revise the E.O. 11246 regulations to reduce paperwork burdens, eliminate unnecessary regulations, and simplify and clarify the regulations while improving the efficiency and effectiveness of the contract compliance program.

Agency Contact:

James I. Melvin
Director, Division of Policy, Planning, and Program Development, OFCCP
Department of Labor
Employment Standards Administration
Room N3424
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-0102
TDD Phone: 202 693-1308
Fax: 202 693-1304
Email: jimelvin@fenix2.dol-esa.gov

RIN: 1215–AA01

DOL—ESA

75. CHILD LABOR REGULATIONS, ORDERS, AND STATEMENTS OF INTERPRETATION (ESA/W-H)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

29 USC 203(e)

CFR Citation:

29 CFR 570

Legal Deadline:

None

Abstract:

Section 3(l) of the Fair Labor Standards Act requires the Secretary of Labor to issue regulations with respect to minors between 14 and 16 years of age ensuring that the periods and conditions of their employment do not interfere with their schooling, health, or well-being. The Secretary is also directed to designate occupations that may be particularly hazardous for minors 16 and 17 years of age. Child Labor Regulation No. 3 sets forth the permissible industries and occupations in which 14- and 15-year-olds may be employed, and specifies the number of hours in a day and in a week, and time periods within a day, that such minors may be employed. The Department has invited public comment in considering whether changes in technology in the workplace and job content over the years require new hazardous occupation orders, and whether changes are needed in some of the applicable hazardous occupation orders. Comment has also been solicited on whether revisions should be considered in the permissible hours and time-of-day standards for 14- and 15-year-olds. Comment has been sought on appropriate changes required to implement school-to-work transition programs. Additionally, Congress enacted Public Law 104-174 (August 6, 1996), which amended FLSA section 13(c) and requires changes in the regulations under Hazardous Occupation Order No. 12 regarding power-driven paper balers and compactors, to allow 16- and 17-year-olds to load, but not operate or unload, machines meeting applicable American National Standards Institute (ANSI) safety standards and certain other conditions. Congress also passed the Drive for Teen Employment Act, Public Law 105-334 (October 31, 1998), which prohibits minors under age 17 from driving automobiles and trucks on public roads on the job and sets criteria for 17-year- olds to drive such vehicles on public roads on the job.

Statement of Need:

Because of changes in the workplace and the introduction of new processes and technologies, the Department is undertaking a comprehensive review of the regulatory criteria applicable to child labor. Other factors necessitating a review of the child labor regulations are changes in places where young workers find employment opportunities, the existence of differing Federal and State standards, and the divergent views on how best to correlate school and work experiences.

Under the Fair Labor Standards Act, the Secretary of Labor is directed to provide by regulation or by order for the employment of youth between 14 and 16 years of age under periods and conditions which will not interfere with their schooling, health and well-being. The Secretary is also directed to designate occupations that may be particularly hazardous for youth between the ages of 16 and 18 years or detrimental to their health or well-being. The Secretary has done so by specifying, in regulations, the permissible industries and occupations in which 14- and 15-year-olds may be employed, and the number of hours per day and week and the time periods within a day in which they may be employed. In addition, these regulations designate the occupations declared particularly hazardous for minors between 16 and 18 years of age or detrimental to their health or well-being.

Public comment has been invited in considering whether changes in technology in the workplace and job content over the years require new hazardous occupation orders or necessitate revision to some of the existing hazardous orders. Comment has also been invited on whether revisions should be considered in the permissible hours and time-of-day standards for the employment of 14- and 15-year-olds, and whether revisions should be considered to facilitate school-to-work transition programs. When issuing the regulatory proposals (after review of public comments on the advance notice of proposed rulemaking), the Department's focus will be on assuring healthy, safe and fair workplaces for young workers, and at the same time promoting job opportunities for young people and making regulatory standards less burdensome to the regulated community.

Summary of Legal Basis:

These regulations are issued under sections 3(1), 11, 12, and 13 of the Fair Labor Standards Act, 29 USC sections 203(1), 211, 212, and 213 which require the Secretary of Labor to issue regulations prescribing permissible time periods and conditions of employment for minors between 14 and 16 years old so as not to interfere with their schooling, health, or well-being, and to designate occupations that may be particularly hazardous or detrimental to the health or well-being of minors under 18 years old.

Alternatives:

Regulatory alternatives developed based on recent legislation and the public comments responding to the advance notice of proposed rulemaking included specific proposed additions or modifications to the paper baler, teen driving, explosive materials, and roofing hazardous occupation orders, and proposed changes to the permissible cooking activities that 14- and 15-year-olds may perform in retail establishments.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits of this regulatory action indicated that the rule was not economically significant. Benefits will include safer working environments and the avoidance of injuries with respect to young workers.

Risks:

The child labor regulations, by ensuring that permissible job opportunities for working youth are safe and healthy and not detrimental to their education as required by the statute, produce positive benefits by reducing health and productivity costs employers may otherwise incur from higher accident and injury rates to young and inexperienced workers. Given the limited nature of the changes in the proposed rule, a detailed assessment of the magnitude of risk was not prepared.

Timetable:

Action	Date	FR Cite
Final Action HOS 2, 10 and 12	11/20/91	56 FR 58626
Final Rule Effective	12/20/91	56 FR 58626
ANPRM	05/13/94	59 FR 25167
ANPRM Comment Period End	08/11/94	
NPRM	11/30/99	64 FR 67130
NPRM Comment Period End	01/31/00	
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

John R. Fraser
Deputy Administrator (WHD)
Department of Labor
Employment Standards Administration
Room S3502
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-0051
Fax: 202 693-1432

RIN: 1215–AA09

DOL—ESA

76. PROCEDURES FOR PREDETERMINATION OF WAGE RATES (29 CFR PART 1) AND LABOR STANDARDS PROVISIONS APPLICABLE TO CONTRACTS COVERING FEDERALLY FINANCED AND ASSISTED CONSTRUCTION (29 CFR PART 5)

Priority:

Economically Significant

Legal Authority:

40 USC 276a to 276a(7)

CFR Citation:

29 CFR 1; 29 CFR 5

Legal Deadline:

None

Abstract:

The Department attempted to implement revised rules governing the circumstances in which ''helpers'' may be used on federally funded and assisted construction contracts subject to the Davis-Bacon Act in May 1982 (see 47 FR 23644, 23658 (May 28, 1982); 47 FR 32090 (July 20, 1982)). After protracted litigation, a final rule was published in January 1989 (see 54 FR 4234) which became effective on February 4, 1991. Thereafter, on two occasions Congress acted to prevent the Department from expending any funds to implement these revised helper regulations—through the Dire Emergency Supplemental Appropriations Act of 1991, PL 102-27, 105 Stat. 130,151 (1991), and then through section 104 of the DOL Appropriations Act of 1994, PL 103-112. Given the uncertainty of continuation of such moratoriums, the Department determined that the helper issue needs to be addressed through further rulemaking. A notice inviting public comment on a proposal to continue the suspension of the former helper regulations while the Department conducts additional rulemaking proceedings was published August 2, 1996 (61 FR 40366). A final rule continuing the suspension while further rulemaking is considered was published December 30, 1996 (61 FR 68641). A notice of proposed rulemaking was published April 9, 1999 (64 FR 17442).

Statement of Need:

The current helper rules are difficult to administer and enforce and—as evidenced by the prolonged litigation history and subsequent congressional actions—are highly controversial. In May 1982, the Department attempted to implement revised rules governing the circumstances in which ''helpers'' may be used on federally funded and assisted construction contracts subject to the Davis-Bacon Act. After protracted litigation, a final rule was published in January 1989 and became effective on February 4, 1991. Thereafter, on two occasions, Congress acted to prevent the Department from expending any funds to implement these revised helper regulations through appropriations riders. Given the uncertainty of continuation of such moratoriums, the Department determined that the helper issue needs to be addressed through further rulemaking.

Summary of Legal Basis:

These regulations are issued under the authority conferred upon the Secretary of Labor by Reorganization Plan No. 14 of 1950 (64 Stat. 1267, 5 USC Appendix) and the Copeland Act (40 USC 276c) in order to provide coordinated enforcement of the prevailing wage provisions of the Davis-Bacon Act (40 USC 276a-276a-7) and several additional Federal statutes that require payment of prevailing wages as determined by the Secretary of Labor according to the Davis-Bacon Act to laborers and mechanics working on federally funded or assisted construction contracts (see list of statutes in 29 CFR sec. 5.1).

Alternatives:

The Administration has determined that there are only limited alternatives to addressing this issue through rulemaking, in addition to possible legislative changes.

Anticipated Cost and Benefits:

A new final rule regarding the helper criteria will seek to make administration of the Davis-Bacon Act more efficient by establishing reasonable ''helper'' criteria and methodology—thus resolving the controversy and uncertainty currently experienced by interested parties. Changes in the helper regulations may affect prior estimates of potential construction procurement cost savings anticipated from the earlier rulemaking. Estimates of the financial impacts of revised ''helper'' regulations included in the NPRM range from $72.8 million to $296 million, depending upon the alternative considered and the data sources used.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM Continue Suspension	08/02/96	61 FR 40367
Final Continue Suspension	12/30/96	61 FR 68641
NPRM	04/09/99	64 FR 17442
NPRM Comment Period End	06/08/99	64 FR 17442
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, State, Local, Tribal

Agency Contact:

John R. Fraser
Deputy Administrator (WHD)
Department of Labor
Employment Standards Administration
Room S3502
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-0051
Fax: 202 693-1432

RIN: 1215–AA94

DOL—Employment and Training Administration (ETA)

FINAL RULE STAGE

77. WELFARE-TO-WORK (WTW) GRANTS

Priority:

Other Significant

Legal Authority:

42 USC 603(a)(5)(c)(ix); PL 106-113, Division B, sec 1000(a)(4)

CFR Citation:

20 CFR 645

Legal Deadline:

Final, Statutory, November 3, 1997, 90 days from enactment.

Other, Statutory, January 1, 2000, for 1999 amendments.

Abstract:

The Employment and Training Administration published interim final regulations on November 18, 1997, implementing the Welfare-to-Work Grants Program. The Personal Responsibility and Work Opportunity Reconciliation Act reformed the Nation's welfare laws, when enacted in August 1996, by creating a new system of block grants to the States for Temporary Assistance for Needy Families (TANF). Moving people from welfare to work is one of the primary goals of Federal welfare policy as well as one of five goals the Secretary of Labor has identified for the Department of Labor. Section 5001 of the Balanced Budget Act of 1997 authorized the Department of Labor to provide Welfare-to-Work Grants to States and local communities to create additional job opportunities for the hardest-to-employ recipients of TANF and certain noncustodial parents. The Welfare-to-Work Grants will be provided to the States through the use of a formula, and in a competitive process to local communities. A small amount of total grant funds will be set aside for special purposes: one percent for Indian tribes; 0.8 percent for evaluation; and $50 million for performance bonuses to successful States.

The interim final regulations and other guidance focus on providing maximum local flexibility. Guidance and regulations reflect minimal amplification of the law and provide further information or clarification as needed to make the program operational. Existing regulations and systems are used wherever possible. Reporting requirements will assure program integrity and provide timely information for tracking performance. Products provided link welfare agencies and workforce development system agencies at the operational level in order to maximize resources available and avoid duplication and overlap. Leveraging of non-Federal resources at the State and local level is encouraged.

These funds will allow States and local communities to help move eligible individuals into jobs by: job creation through public or private sector wage subsidies; on-the-job training; contracts with public or private providers of job readiness, job placement, and post-employment services; job vouchers for similar services; community service or work experience; or job retention and supportive services (if such services are not otherwise available).

Statement of Need:

Since the passage of the Personal Responsibility and Work Opportunity Reconciliation Act, the President and the Congress recognized the need for a measure to complement the Temporary Assistance for Needy Families (TANF) block grant created as a result of the Act. On August 5, 1997, President Clinton signed into law the Balanced Budget Act of 1997, which authorized the Department of Labor to provide Welfare-to-Work Grants to States and local communities to create additional job opportunities for the hardest-to-employ recipients of TANF. The basic goal of the program is to move welfare recipients into unsubsidized jobs with good career potential for economic self-sufficiency. Welfare-to-Work formula and competitive grants provide States and local communities with an array of tools to help them accomplish this goal in ways that make sense and are most effective for their particular population needs. The Employment and Training Administration will issue final

regulations and other guidance, provide technical assistance, and establish performance standards which will drive State and local efforts towards the program's goal while still allowing maximum local flexibility. The passage of the Welfare-to-Work and Child Support Amendments of 1999 will necessitate the publication of a new interim final rule to reflect the changes in eligibility and certain other areas.

Summary of Legal Basis:

Promulgation of these regulations is authorized by SSA section 403 (a)(1)(5)(C)(ix). Section 801(f) of HR 3424, the Welfare-to-Work and Child Support Amendments of 1999, enacted by section 1000(a)(4) of Division B of the Consolidated Appropriations Act for August 2000 (PL 106-113) authorizes interim final regulations to implement the changes made by those amendments.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs of this regulatory action have not been determined at this time and will be determined at a later date. Welfare recipients will receive job placement and temporary, transitional employment opportunities leading to lasting employment and self-sufficiency. Employers will have ready access to a large pool of motivated hard-working entry-level workers who will be eligible for job retention and support services to maintain employment. Businesses will be eligible to receive wage and on-the-job training subsidies when they hire the hard-to-employ welfare recipients.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/18/97	62 FR 61587
Interim Final Rule	10/00/00	
Final Rule	10/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

State, Local, Tribal

Agency Contact:

Dennis Lieberman
Director, Division of Welfare to Work
Department of Labor
Employment and Training Administration
200 Constitution Avenue NW
N4671, FP Building
Washington, DC 20210
Phone: 202 219-7694

RIN: 1205–AB15

DOL—Pension and Welfare Benefits Administration (PWBA)

FINAL RULE STAGE

78. REGULATIONS IMPLEMENTING THE HEALTH CARE ACCESS, PORTABILITY AND RENEWABILITY PROVISIONS OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

PL 104-91 section 101; 29 USC 1027; 29 USC 1059; 29 USC 1135; 29 USC 1171; 29 USC 1172; 29 USC 1177

CFR Citation:

29 CFR 2590

Legal Deadline:

Other, Statutory, April 1, 1997, Interim Final Rule.

Per section 734 of ERISA as added by section 101 of HIPAA.

Abstract:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) amended title I of ERISA by adding a new part 7, designed to improve health care access, portability and renewability. This rulemaking will provide regulatory guidance to implement these provisions.

Statement of Need:

HIPAA added a new part 7 to title I of ERISA, containing provisions designed to improve the availability and portability of health insurance coverage. Part 7 includes provisions limiting exclusions for preexisting conditions and providing credit for prior coverage, guaranteeing availability of health coverage for small employers, prohibiting discrimination against employees and dependents based on health status, and guaranteeing renewability of health coverage to employers and individuals.

Summary of Legal Basis:

Promulgation of these regulations is authorized by sections 505 and 734 of ERISA.

Alternatives:

Regulatory alternatives will be developed once determinations have been made, in conjunction with other concerned agencies with regard to the scope and nature of the final regulatory guidance which will be necessary to carry out the new provisions.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits of the regulatory actions found to be necessary to implement the new provision will be developed once decisions are reached on which specific actions are necessary.

Risks:

Failure to provide regulatory guidance necessary to carry out these important health care reforms would adversely impact the availability and portability of health insurance coverage for American families.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16894
Interim Final Rule Effective	06/07/97	
Interim Final Rule Comment Period End	07/07/97	
Request for Information	10/25/99	64 FR 57520
Comment Period End	01/25/00	
Final Rule	07/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

Daniel J. Maguire
Director, Office of Health Plan Standards
Department of Labor
Pension and Welfare Benefits Administration
Room N5677
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 219-4592

RIN: 1210–AA54

DOL—PWBA

79. AMENDMENT OF SUMMARY PLAN DESCRIPTION AND RELATED ERISA REGULATIONS TO IMPLEMENT STATUTORY CHANGES IN THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

Priority:

Other Significant

Legal Authority:

PL 104-191 sec 101; PL 104-204 sec 603

CFR Citation:

29 CFR 2520.102-3; 29 CFR 2520.104b-1; 29 CFR 2520.104b-3

Legal Deadline:

NPRM, Statutory, April 1, 1997, Per sections 707 and 734 of ERISA as added by section 101 of HIPAA.

Abstract:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) amended ERISA's summary plan description (SPD) and related reporting and disclosure provisions to require that participants and beneficiaries receive from their group health plans: (i) more timely notice if there is a material reduction in services or benefits under the plan; (ii) more information regarding the financing and administration of the plan; and (iii) specific identification of Department of Labor offices through which they can seek assistance or information about HIPAA. The Newborns' and Mothers' Health Protection Act of 1996 (NMHPA) also amended ERISA's SPD and related reporting and disclosure provisions. This rulemaking will amend the Department's SPD and related regulations to implement those statutory changes.

Statement of Need:

The existing SPD and related reporting and disclosure provisions need to be revised to reflect the changes made by HIPAA. HIPAA's statutory changes modify the requirements concerning the manner and timing of how certain important plan information is communicated to participants and beneficiaries by plan administrators. Without revised regulatory guidance administrators may not be able to improve the timely disclosure of plan information on both a quantitative and qualitative basis. HIPAA also requires the Secretary to issue regulations within 180 days after its enactment providing alternative mechanisms to delivery by mail through which group health plans may notify participants and beneficiaries of material reductions in covered services or benefits.

Summary of Legal Basis:

Promulgation of these regulations is authorized by sections 104(b), 505 and 734 of ERISA.

Alternatives:

Regulatory alternatives will be developed once determinations have been made with regard to the scope and nature of the regulatory guidance which will be necessary to carry out the new provisions.

Anticipated Cost and Benefits:

There is estimated to be no capital/start-up cost. Total burden cost for operating/maintenance is estimated to average $73,000,000 annually for the years 1997, 1998, and 1999. However, the Department believes that the regulation, which implements requirements under HIPAA, assures that participants have better access to more complete information about their benefit plans.

Risks:

The SPD is a critical plan document for participants and beneficiaries. Without access to accurate and timely information participants and beneficiaries will not be able to protect their rights under ERISA. Improved disclosure requirements also should serve to facilitate compliance by plan administrators, thereby reducing litigation and penalty risks to plan administrators. The failure to issue revised disclosure regulations also may result in a failure to achieve HIPAA's objective of improving the disclosure of plan information.

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/08/97	62 FR 16979
Interim Final Rule Comment Period End	05/31/97	
Interim Final Rule Effective	06/01/97	
Second Interim Final Rule	09/09/98	63 FR 48372
Interim Final Rule Effective	11/09/98	
Comment Period End	11/09/98	
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

Eric A. Raps
Pension Law Specialist
Department of Labor
Pension and Welfare Benefits Administration
Room N5669
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 219-8521

RIN: 1210–AA55

DOL—PWBA

80. AMENDMENTS TO EMPLOYEE BENEFIT PLAN CLAIMS PROCEDURES REGULATION

Priority:

Other Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

29 USC 1133; 29 USC 1135

CFR Citation:

29 CFR 2560.503-1

Legal Deadline:

None

Abstract:

The Department has proposed to amend the regulation governing the establishment and maintenance of benefit claims procedures by employee benefit plans covered by title I of the Employee Retirement Income Security Act (ERISA). The amendment would establish new standards for the processing of group health and other employee benefit plan claims filed by participants and beneficiaries. In the case of group health plans, as well as certain plans providing disability benefits, the new standards are intended to ensure more timely benefit determinations, improved access to information on which a benefit determination is based, and greater assurance that participants and beneficiaries will be afforded a full and fair review of denied claims.

Statement of Need:

This regulation is necessary to insure more timely benefit determinations, improve access to information on which a benefit determination is made, and provide greater assurance that participants and beneficiaries will be afforded a full and fair review of denied claims.

Summary of Legal Basis:

Promulgation of this regulation is authorized by sections 503 and 505 of ERISA.

Alternatives:

Regulatory alternatives will be developed once determinations have been made with regard to the scope and nature of the amendments necessary to update the rules that implement section 503 of ERISA.

Anticipated Cost and Benefits:

In publishing the proposed regulations, the Department estimated that the projected benefits of the proposal would outweigh its projected costs. In particular, updating the existing regulation to address recent changes in the delivery and financing of health care services would improve health care quality by averting harmful, inappropriate delays and denials of health benefits thereby yielding substantial social benefits.

Risks:

Failure to issue this regulation would deprive many plan participants and beneficiaries of the benefits of an improved claims review process.

Timetable:

Action	Date	FR Cite
Request for Information--Amendment of Regulations on Plan Claims Procedures	09/08/97	62 FR 47262
Comment Period End	11/07/97	
NPRM	09/09/98	63 FR 48390
NPRM Comment Period End	11/09/98	
Notice of Public Hearing Held on Feb. 17,18 & 19, 1999	01/04/99	64 FR 65
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Susan M. Halliday
Pension Law Specialist
Department of Labor
Pension and Welfare Benefits Administration
Room N5669
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 219-8671

RIN: 1210–AA61

DOL—PWBA

81. AMENDMENTS TO SUMMARY PLAN DESCRIPTION REGULATIONS

Priority:

Other Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 1024; 29 USC 1135

CFR Citation:

29 CFR 2520.102-3; 29 CFR 2520.102-5

Legal Deadline:

None

Abstract:

These amendments to the regulations governing the contents of summary plan descriptions (SPD) will ensure that all participants in group health plans are provided, consistent with the recommendations of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, understandable information concerning their plan; provider network composition; preauthorization and utilization review procedures; whether, and under what circumstances, coverage is provided for existing and new drugs; and whether, and under what circumstances, coverage is provided for experimental drugs, devices, and procedures. These amendments will repeal special rules limiting the information that must be included in summary plan descriptions with respect to certain health maintenance organizations. In addition, the amendments include provisions that update or clarify the application of certain SPD content requirements affecting both pension and welfare benefit plans.

Statement of Need:

This regulation is necessary to improve the disclosure of group health plan benefit information, consistent with the recommendations of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, as set forth in its November 20, 1997 report. The amendments will also update the general SPD content requirements and update other relevant regulatory provisions.

Summary of Legal Basis:

Promulgation of this regulation is authorized by sections 101(a), 102(b), and 505 of ERISA.

Alternatives:

Regulatory alternatives will be developed once determinations have been made with regard to the scope and nature of the amendments which are necessary to improve the disclosure of benefit information to participants and beneficiaries of group health plans under the applicable ERISA regulations.

Anticipated Cost and Benefits:

The Department estimates that the regulation's benefits will exceed its costs. The regulation would assure that participants have better access to more complete information on their benefit plans. Better information will lead both participants and plan sponsors to make more economically efficient decisions regarding benefit plans. This enhanced value and efficiency from better information constitute the benefits of the regulation.

Risks:

Failure to issue the regulation would deprive participants, beneficiaries, and plan sponsors of the improvements in health care market efficiency which would be generated by the regulatory amendments specified therein.

Timetable:

Action	Date	FR Cite
NPRM	09/09/98	63 FR 48376
NPRM Comment Period End	11/09/98	
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Organizations

Government Levels Affected:

None

Agency Contact:

John J. Canary
Supervisory Pension Law Specialist
Department of Labor
Pension and Welfare Benefits Administration
Room N5669
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 219-8521

RIN: 1210–AA69

DOL—Mine Safety and Health Administration (MSHA)

FINAL RULE STAGE

82. DIESEL PARTICULATE MATTER (EXPOSURE OF UNDERGROUND COAL MINERS)

Priority:

Other Significant

Legal Authority:

30 USC 811; 30 USC 813

CFR Citation:

30 CFR 72; 30 CFR 75

Legal Deadline:

None

Abstract:

Epidemiological studies indicate that diesel exhaust presents potential health risks to workers ranging from headaches and nausea to respiratory disease and cancer. The National Institute for Occupational Safety and Health considers whole diesel exhaust to be a potential occupational carcinogen. The International Agency for Research on Cancer found that diesel engine exhaust is probably carcinogenic to humans.

The rule as proposed for underground coal mines requires the use of filtration to remove diesel particulate matter, and requires the use of ''best practice controls'' to reduce diesel particulate matter.

Statement of Need:

The use of diesel-powered equipment in underground mines has increased significantly and rapidly during the past decade. We estimate that approximately 13,000 miners are occupationally exposed to diesel exhaust emissions in underground coal mines. Several epidemiological studies have shown a positive carcinogenic risk associated with exposure to diesel exhaust. Other reported health effects associated with exposure to diesel exhaust include dizziness, drowsiness, headaches, nausea, decreased visual acuity, and decreased forced expiratory volume. In addition, studies by MSHA and the former Bureau of Mines show that miners working in underground mining operations that use diesel equipment are probably the most heavily exposed workers of any occupational group. Based on the levels of diesel particulate measured in underground mining operations and the evidence of adverse health effects associated with exposure to diesel exhaust, we are concerned about the potential health risk to miners.

Summary of Legal Basis:

Promulgation of these regulations is authorized by sections 101, 103, and 508 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

In the fall of 1995, we held a series of public workshops to gather suggestions for possible approaches to limit miners' exposure to diesel particulate. In addition, over the past 10 years, MSHA and the former Bureau of Mines have conducted research on methodologies for the measurement and control of diesel particulate in the mining environment. This research has demonstrated that the use of low sulfur fuel, good engine maintenance, exhaust after-treatment, new engine technology, and optimized application of ventilating air all play a role in reducing miners' exposure to diesel exhaust particulate matter.

We considered establishing a PEL for diesel particulate in coal mines, but found that technology for measuring it in the presence of coal mine dust is not currently feasible. Therefore, the use of filtration to remove diesel particulate matter is required by the proposed rule.

Anticipated Cost and Benefits:

We estimate that the per year compliance costs are just over $10 million, of which underground coal mine operators would incur about $10 million and manufacturers of diesel engines and equipment would incur about $14,000.

The proposed rule would reduce a significant health risk to underground miners, reducing the potential for acute sensory irritations and respiratory symptoms, lung cancer, and premature death, along with the attendant suffering and costs to the miners, their families, and society. In addition to savings related to acute health effects, we estimate that some lung cancers would also be avoided.

Risks:

Several epidemiological studies have found that exposure to diesel exhaust presents potential health risks to workers. These potential adverse health effects range from headaches and nausea to respiratory disease and cancer. In the confined space of the underground mine environment, occupational exposure to diesel exhaust may present a greater hazard due to ventilation limitations and the presence of other airborne contaminants, such as toxic mine dusts or mine gases. We believe that the health evidence forms a reasonable basis for reducing miners' exposure to diesel particulate.

Timetable:

Action	Date	FR Cite
ANPRM	01/06/92	57 FR 500
ANPRM Comment Period End	07/10/92	
NPRM	04/09/98	63 FR 17492
Notice Significant Environment Impact	07/14/98	63 FR 37796
Extension of Comment Period; Notice of Hearings; Close of Record	08/05/98	63 FR 41755
Notice of Hearings; Close of Record	10/19/98	63 FR 55811
Extension of Comment Period; Availability of Studies; Close of Record	02/12/99	64 FR 7144
Extension of Comment Period; Close of Record	04/27/99	64 FR 2259
Corrections	07/08/99	64 FR 36826
Availability of Documents; Request for Comments	06/30/00	65 FR 40557
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Carol J. Jones
Director, Office of Standards
Department of Labor
Mine Safety and Health Administration
Room 631
4015 Wilson Boulevard
Arlington, VA 22203
Phone: 703 235-1910
Fax: 703 235-5551
Email: jones-carol@msha.gov

RIN: 1219–AA74

DOL—MSHA

83. DIESEL PARTICULATE MATTER (EXPOSURE OF UNDERGROUND METAL AND NONMETAL MINERS)

Priority:

Other Significant

Legal Authority:

30 USC 811; 30 USC 813

CFR Citation:

30 CFR 57

Legal Deadline:

None

Abstract:

Epidemiological studies indicate that diesel exhaust presents potential health risks to workers ranging from headaches and nausea to respiratory disease and cancer. The National Institute for Occupational Safety and Health considers whole diesel exhaust to be a potential occupational carcinogen. The International Agency for Research on Cancer found that diesel engine exhaust is probably carcinogenic to humans.

The rule as proposed for underground metal and nonmetal mines would establish a concentration limit for diesel particulate matter and require the use of engineering and work practice controls to reduce diesel particulate matter.

Statement of Need:

The use of diesel-powered equipment in underground mines has increased significantly and rapidly during the past decade. We estimate that about 7,500 miners working in production or development areas are occupationally exposed to diesel exhaust emissions in underground metal and nonmetal mines.

Several epidemiological studies have shown a positive carcinogenic risk associated with exposure to diesel exhaust. Other reported health effects associated with exposure to diesel exhaust include dizziness, drowsiness, headaches, nausea, decreased visual activity, and decreased forced expiratory volume. In addition, studies by MSHA and the former Bureau of Mines show that miners working in underground mining operations that use diesel equipment are probably the most heavily exposed workers of any occupational group. Based on the levels of diesel particulate measured in underground mining operations and the evidence of adverse health effects associated with exposure to diesel exhaust. We are concerned about the potential health risk to miners.

Summary of Legal Basis:

Promulgation of these regulations is authorized by sections 101 and 103 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

In the fall of 1995, we held a series of public workshops to gather suggestions for possible approaches to limit miners' exposure to diesel particulate. In addition, over the past 10 years, MSHA and the former Bureau of Mines have conducted research on methodologies for the measurement and control of diesel particulate in the mining environment. This research has demonstrated that the use of low sulfur fuel, good engine maintenance, exhaust after-treatment, new engine technology, and optimized application of ventilating air all play a role in reducing miners' exposure to diesel exhaust particulate matter.

Anticipated Cost and Benefits:

We estimate that the compliance costs for underground metal and nonmetal operators would be approximately $19 million. The compliance costs to manufacturers are assumed to be passed through to underground metal and nonmetal operators and therefore, they would not incur any direct costs as a result of the rule.

The proposed rule would reduce a significant health risk to underground miners, reducing the potential for acute sensory irritations and respiratory symptoms, lung cancer, and premature death, along with the attendant suffering and costs to the miners, their families, and society. In addition to savings related to acute health effects, we estimate that some lung cancer would also be avoided.

Risks:

Several epidemiological studies have found that exposure to diesel exhaust presents potential health risks to workers. These potential adverse health effects range from headaches and nausea to respiratory disease and cancer. In the confined space of the underground mine environment, occupational exposure to diesel exhaust may present a greater hazard due to ventilation limitations and the presence of other airborne contaminants, such as toxic mine dusts or mine gases. We believe that the health evidence forms a reasonable basis for reducing miners' exposure to diesel particulate.

Timetable:

Action	Date	FR Cite
ANPRM	01/06/92	57 FR 500
ANPRM Comment Period End	07/10/92	
NPRM	10/29/98	63 FR 58104
Extension of Comment Period; Availability of Studies; Close of Record	02/12/99	64 FR 7144
Notice of Hearings; Close of Record	03/24/99	64 FR 14200
Corrections	07/08/99	64 FR 36826
Availability of Documents; Request for Comments	06/30/00	65 FR 40557
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Carol J. Jones
Director, Office of Standards
Department of Labor
Mine Safety and Health Administration
Room 631
4015 Wilson Boulevard
Arlington, VA 22203
Phone: 703 235-1910
Fax: 703 235-5551
Email: jones-carol@msha.gov

RIN: 1219–AB11

DOL—MSHA

84. VERIFICATION OF UNDERGROUND COAL MINE OPERATORS' DUST CONTROL PLANS AND COMPLIANCE SAMPLING FOR RESPIRABLE DUST

Priority:

Other Significant

Legal Authority:

30 USC 811

CFR Citation:

30 CFR 70; 30 CFR 75; 30 CFR 90

Legal Deadline:

None

Abstract:

Our current regulations require that all underground coal mine operators develop and follow a mine ventilation plan that we approve for each mechanized mining unit. However, we do not have a requirement that provides for verification of each plan's effectiveness under typical mining conditions. Consequently, plans may be implemented by mine operators that could be inadequate to control respirable dust. The proposed rule provides for MSHA to verify the effectiveness of mine ventilation plans to control respirable dust under typical mining conditions. For longwall mine operators, we proposed to permit the limited use of either approved loose-fitting powered, air purifying respirators (PAPRS) or verifiable administrative controls as a supplemental means of compliance if we have determined that further reduction in respirable dust levels cannot be achieved using all feasible engineering controls. Furthermore, MSHA proposed to assume responsibility for all compliance sampling for respirable dust in underground coal mines as required under CFR parts 70 and 90. The proposed rule also discusses our long term objective to use continuous monitoring for sampling.

Statement of Need:

Respirable coal mine dust levels in this country are significantly lower than they were two decades ago. Despite this progress, there continues to be concern about the respirable coal mine dust sampling program and its effectiveness in maintaining exposure levels in mines at or below the applicable standard. Our regulations require that all underground coal mine operators develop and follow a mine ventilation plan approved by us. The dust control portion of the mine ventilation plan is the key element of an operator's strategy to control respirable dust in the work environment. Although such plans are required to be designed to control respirable dust, there is no current requirement that provides for verification of each proposed plan's effectiveness under typical mining conditions. Consequently, plans may be implemented that may be inadequate to control respirable dust.

Therefore, we proposed to revoke existing operator respirable dust sampling and to implement new regulations that would require each underground coal mine operator to have a verified ventilation plan. MSHA would verify the effectiveness of the mine ventilation plan for each mechanical mining unit in controlling respirable dust under typical mining conditions.

Summary of Legal Basis:

Promulgation of these regulations is authorized by section 101 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

In developing the proposed rule, we considered alternatives related to typical production levels and the use of appropriate dust control strategies, use of supplemental controls for mining entities other than longwalls, and the level of protection of loose-fitting powered air purifying respirators (PAPRS) in underground coal mines.

Anticipated Cost and Benefits:

Benefits sought are eliminating coal workers' pneumoconiosis by reducing over-exposures to respirable coal dust on each and every production shift. Additional benefits include: reduced health care costs, disability and black lung benefit payments. There would be a cost savings for mine operators when MSHA completely takes over compliance and abatement sampling for respirable dust once this rule is promulgated. We developed estimates and made them available for public review.

Risks:

Respirable coal mine dust is one of the most serious occupational hazards in the mining industry. Long-term exposure to excessive levels of respirable coal mine dust can cause black lung and silicosis, which are potentially disabling and can cause death. We are pursuing both regulatory and nonregulatory actions to eliminate these diseases through the control of coal mine respirable dust levels in mines and the reduction of miners' exposure.

Timetable:

Action	Date	FR Cite
NPRM	07/07/00	65 FR 42122
Notice of Hearings; Close of Record	07/07/00	65 FR 42186
Extension of Comment Period; Close of Record	08/11/00	65 FR 49215
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

This rulemaking is related to RIN 1219-AB18.

Agency Contact:

Carol J. Jones
Director, Office of Standards
Department of Labor
Mine Safety and Health Administration
Room 631
4015 Wilson Boulevard
Arlington, VA 22203
Phone: 703 235-1910
Fax: 703 235-5551
Email: jones-carol@msha.gov

RIN: 1219–AB14

DOL—MSHA

85. DETERMINATION OF CONCENTRATION OF RESPIRABLE COAL MINE DUST

Priority:

Other Significant

Legal Authority:

30 USC 811

CFR Citation:

30 CFR 72

Legal Deadline:

None

Abstract:

The National Institute for Occupational Safety and Health and the Mine Safety and Health Administration jointly determined that a single, full-shift measurement (''single, full-shift sample'') would accurately represent the atmospheric conditions to which a miner is exposed. The proposed rule will address the U.S. Court of Appeals' final decision and order in National Mining Association v. Secretary of Labor, 153 F3d 1264 (11th Cir. 1998).

Statement of Need:

Respirable coal mine dust levels in this country are significantly lower than

they were two decades ago. Despite this progress, there continues to be concern about our current sampling programs'ability to accurately measure and maintain respirable coal mine dusts exposure at or below the applicable standard on each shift. For as long as miners have taken coal from the ground, many have suffered respiratory problems due to their exposures to respirable coal mine dust. These respiratory problems affect the current workforce and range from mild impairment of respiratory function to more severe diseases, such as silicosis and pulmonary massive fibrosis. For some miners, the impairment of their respiratory systems is so severe, they die prematurely. Since there is a clear relationship between a miner's cumulative exposure to respirable coal mine dust and the severity of the resulting respiratory conditions it is imperative that each miner's exposure not exceed the applicable standard on each and every shift.

Summary of Legal Basis:

Promulgation of these regulations is authorized by section 101 of the Federal Mine Safety and Health Act of 1977.

Alternatives:

The requirements of this rule (''single, full-shift sample rule'') will work in tandem with those of the proposed rule (RIN 1219-AB14) in which MSHA would verify the effectiveness of ventilation plans as well as conduct all compliance sampling in underground coal mines.

Anticipated Cost and Benefits:

Benefits sought are eliminating coal workers pneumoconiosis by over-exposures to respirable coal dust on each and every production shift. Additional benefits include: reduced health care costs, disability and black lung benefit payments. There would be a cost savings for mine operators when MSHA completely takes over compliance and abatement sampling for respirable dust once this rule is promulgated. We have developed cost estimates and have made them available for public review.

Risks:

Respirable coal mine dust is one of the most serious occupational hazards in the mining industry. Occupational exposure to excessive levels of respirable coal mine dust can cause coal workers' pneumoconiosis and silicosis, which are potentially disabling and can cause death. We are pursuing both regulatory and nonregulatory actions to eliminate these diseases through the control of coal mine respirable dust levels in mines and reduction of miners' exposure.

Timetable:

Action	Date	FR Cite
NPRM	07/07/00	65 FR 42068
Notice of Hearings; Close of Record	07/07/00	65 FR 42185
Extension of Comment Period; Close of Record	08/11/00	65 FR 49215
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

This rulemaking is related to RIN 1219-AB14 (Verification of Underground Coal Mine Operators' Dust Control Plans and Compliance Sampling for Respirable Dust).

Agency Contact:

Carol J. Jones
Director, Office of Standards
Department of Labor
Mine Safety and Health Administration
Room 631
4015 Wilson Boulevard
Arlington, VA 22203
Phone: 703 235-1910
Fax: 703 235-5551
Email: jones-carol@msha.gov

RIN: 1219–AB18

DOL—Occupational Safety and Health Administration (OSHA)

PROPOSED RULE STAGE

86. SAFETY AND HEALTH PROGRAMS (FOR GENERAL INDUSTRY AND THE MARITIME INDUSTRIES)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 651; 29 USC 655; 29 USC 657

CFR Citation:

29 CFR 1910; 29 CFR 1915; 29 CFR 1917; 29 CFR 1918

Legal Deadline:

None

Abstract:

The Occupational Safety and Health Administration (OSHA), many of the States, members of the safety and health community, insurance companies, professional organizations, companies participating in the Agency's Voluntary Protection Programs, and many proactive employers in all industries recognize the value of worksite-specific safety and health programs in preventing job-related injuries, illnesses, and fatalities. The reductions in job-related injuries and illnesses, workers' compensation costs, and absenteeism that occur after employers implement such programs dramatically demonstrate the effectiveness of these programs. In 1989, OSHA published nonmandatory guidelines to help employers establish safety and health programs (54 FR 3904). Those guidelines were based on a distillation of the best safety and health management practices observed by OSHA in the years since the Agency was established. OSHA has decided to expand on these guidelines by developing a safety and health programs rule because occupational injuries, illnesses, and fatalities are continuing to occur at an unacceptably high rate. For example, an average of about 17 workers were killed each day in 1997. This number does not include an estimated 137 daily deaths associated with job-related chronic illnesses.

Safety and health programs include the following core elements: management leadership; active employee participation; hazard identification and assessment; hazard prevention and control; information and training; and program evaluation. In response to extensive stakeholder involvement, OSHA has, among other things, focused the proposed rule on significant hazards and reduced burdens on small business to the extent consistent with the goals of the OSH Act.

Statement of Need:

Worksite-specific safety and health programs are increasingly being recognized as the most effective way of reducing job-related accidents, injuries, and illnesses. Many States have to date passed legislation and/or regulations mandating such programs

for some or all employers, and insurance companies have also been encouraging their client companies to implement these programs, because the results they have achieved have been dramatic. In addition, all of the companies in OSHA's Voluntary Protection Programs have established such programs and are reporting injury and illness rates that are sometimes only 20 percent of the average for other establishments in their industry. Safety and health programs apparently achieve these results by actively engaging front-line employees, who are closest to operations in the workplace and have the highest stake in preventing job-related accidents, in the process of identifying and correcting occupational hazards. Finding and fixing workplace hazards is a cost-effective process, both in terms of the avoidance of pain and suffering and the prevention of the expenditure of large sums of money to pay for the direct and indirect costs of these injuries and illnesses. For example, many employers report that these programs return between $5 and $9 for every dollar invested in the program, and almost all employers with such programs experience substantial reductions in their workers' compensation premiums. OSHA believes that having employers evaluate the job-related safety and health hazards in their workplace and address any hazards identified before they cause occupational injuries, illnesses, or deaths is an excellent example of ''regulating smarter,'' because all parties will benefit: workers will avoid the injuries and illnesses they are currently experiencing; employers will save substantial sums of money and increase their productivity and competitiveness; and OSHA's scarce resources will be leveraged as employers and employees join together to identify, correct, and prevent job-related safety and health hazards.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary finding by the Secretary of Labor that unacceptably high injury, illness, and fatality rates can be substantially reduced by getting employers to systematically comply with their existing duty to control hazards under sections 5(a)(1) and 5(a)(2) of the OSH Act. The rule is also reasonably related to achieving the purposes of the Act, and would essentially require employers to conduct periodic inspections of the workplace and to inform employees about the hazards they find.

Alternatives:

In the last few years, OSHA has considered both nonregulatory and regulatory alternatives in the area of safety and health program management. First, in 1989, OSHA published a set of voluntary management guidelines designed to help employers set up and maintain safety and health programs. Although these guidelines have received widespread praise from many employers and professional safety and health associations, they have not been adequately effective in reducing job-related deaths, injuries, and illnesses, which have continued to occur at unacceptably high levels. Many States have also recognized the value of these programs and have mandated that some or all employers establish them; this has led to inconsistent coverage from State to State, with many States having no coverage and others imposing stringent program requirements.

Anticipated Cost and Benefits:

OSHA preliminarily estimated the overall program costs of the draft proposed rule provided to the SBREFA Panel for this rule for all covered employers to be about $2.3 billion per year. The Agency also preliminarily estimated that 580,000 to 1,300,000 injuries and illnesses and 416 to 918 fatalities would be avoided each year as a result of the rule. OSHA preliminarily anticipates that employers will have direct cost savings associated with this reduction in the number of injuries and illnesses of approximately $7.3 billion to $16.5 billion per year.

Risks:

Workers in all major industry sectors in the United States continue to experience an unacceptably high rate of occupational fatalities, injuries, and illnesses. For 1996, the Bureau of Labor Statistics reported that 6.2 million injuries and illnesses occurred within private industry. For 1997, BLS reported that 6,218 workers lost their lives on the job. There is increasing evidence that addressing hazards in a piecemeal fashion, as employers tend to do in the absence of a comprehensive safety and health program, is considerably less effective in reducing accidents than a systematic approach. Dramatic evidence of the seriousness of this problem can be found in the staggering workers' compensation bill paid by America's employers and employees: about $54 billion annually. These risks can be reduced by the implementation of safety and health programs, as evidenced by the experience of OSHA's Voluntary Protection Program participants, who regularly achieve injury and illness rates averaging one-fifth to one-third those of competing firms in their industries. Because the proposed rule addresses significant job-related hazards, the rule will be effective in ensuring a systematic approach to the control of long-recognized hazards, such as lead, which are covered by existing OSHA standards, and emerging hazards, such as lasers and violence in the workplace, where conditions in the workplace would require control under the General Duty Clause of the Act.

Timetable:

Action	Date	FR Cite
NPRM	09/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State

Federalism:

Undetermined

Additional Information:

A separate rule is being developed for the construction industry (29 CFR 1926). OSHA will coordinate the development of the two rules.

Agency Contact:

Marthe B. Kent
Director, Directorate of Safety Standards Programs
Department of Labor
Occupational Safety and Health Administration
Room N3609
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-2222
Fax: 202 693-1663

RIN: 1218–AB41

DOL—OSHA

87. OCCUPATIONAL EXPOSURE TO CRYSTALLINE SILICA

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

29 USC 655(b); 29 USC 657

CFR Citation:

29 CFR 1910; 29 CFR 1926; 29 CFR 1915; 29 CFR 1916; 29 CFR 1917; 29 CFR 1918

Legal Deadline:

None

Abstract:

Silica exposure remains a serious threat to nearly 2 million U.S. workers, including more than 100,000 workers in high risk jobs such as abrasive blasting, foundry work, stonecutting, rock drilling, quarry work and tunneling. The seriousness of the health hazards associated with silica exposure is demonstrated by the fatalities and disabling illnesses that continue to occur in sandblasters and rock drillers and by recent studies that demonstrate a statistically significant increase in lung cancer among silica-exposed workers. In October 1996, the International Agency for Research on Cancer classified crystalline silica as ''carcinogenic to humans.'' Exposure studies indicate that some workers are still exposed to very high levels of silica. Although OSHA currently has a permissible exposure limit for crystalline silica (10 mg/m3 divided by the percent of silica in the dust (respirable + 2)), more than 30 percent of OSHA-collected silica samples from 1982 through 1991 exceeded this limit. Additionally recent studies suggest that the current OSHA standard is insufficient to protect against silicosis. OSHA plans to publish a proposed rule on crystalline silica under section 6(b)(5) of the Act. The standard would protect silica-exposed workers in general industry, construction and maritime.

Statement of Need:

The current OSHA permissible exposure limit for silica is 10 mg/m3 divided by the percent of silica in the dust + 2 (respirable) and 30 mg/m3 divided by the percent of silica in the dust + 2 (total dust). In the interval since this limit was promulgated there have been a number of studies of workers that have estimated that close to 50 percent of workers exposed to silica at the current limit for a 45-year working lifetime would develop silicosis, a disabling, progressive and sometimes fatal disease involving scarring of the lung, coughing, and shortness of breath. There are currently about 300 deaths reported per year from silicosis. However, the actual number of cases and the true risk is unknown due to inadequate case identification, which means that the number of deaths is probably underreported. Also, since the promulgation of OSHA's permissible exposure limit, studies have demonstrated a statistically significant, dose-related increase in lung cancer in several occupational groups.

Because of these recent findings, OSHA believes that it will be necessary to conduct a risk assessment to determine whether the current permissible exposure limit is protective of worker health. OSHA also believes that, in addition to the permissible exposure limit, the ancillary provisions, such as engineering controls, provided by a comprehensive standard will be necessary to reduce worker exposure to crystalline silica.

Summary of Legal Basis:

The legal basis for the proposed rule is a preliminary determination by the Secretary of Labor that exposure to silica at the Agency's current permissible exposure limits poses a significant risk of material impairment of health and that a standard will substantially reduce that risk.

Alternatives:

OSHA has considered or conducted several programs designed to reduce worker exposure to crystalline silica. The OSHA Special Emphasis Program for Silicosis provides inspection targeting to reduce or eliminate workplace exposures to crystalline silica. The National Campaign to Eliminate Silicosis being conducted by OSHA (in conjunction with the National Institute for Occupational Safety and Health, the Mine Safety and Health Administration, and the American Lung Asssociation) is an ongoing program involving outreach and education and the dissemination of materials on methods to reduce worker exposure to crystalline silica. Other nonregulatory approaches might include the issuance of nonmandatory guidelines, enforcing lower limits through the ''general duty'' clause of the OSH Act in cases where substantial evidence exists that exposure presents a recognized hazard of death or serious physical harm, and the issuance of hazard alerts. Although these approaches may be partially effective in reducing worker exposure to crystalline silica and reducing disease risk, OSHA believes that progress in the prevention of silica-related diseases demands the issuance of a comprehensive silica standard.

Anticipated Cost and Benefits:

The scope of the proposed rule is currently under development and thus quantitative estimates of costs and benefits have not been determined at this time.

Risks:

OSHA has not yet completed an assessment of the risks of exposure to crystalline silica. Other studies have shown risks ranging from 35 to 47 percent among workers exposed over a working lifetime and have additionally identified silica as a potential occupational carcinogen.

Timetable:

Action	Date	FR Cite
NPRM	09/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Agency Contact:

Marthe B. Kent
Acting Director, Directorate of Health Standards Programs
Department of Labor
Occupational Safety and Health Administration
Room N3718
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-1950
Fax: 202 693-1678

RIN: 1218–AB70

DOL—OSHA

FINAL RULE STAGE

88. STEEL ERECTION (PART 1926) (SAFETY PROTECTION FOR IRONWORKERS)

Priority:

Economically Significant. Major under 5 USC 801.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

29 USC 655; 40 USC 333

CFR Citation:

29 CFR 1926.750 (Revision); 29 CFR 1926.751 (Revision); 29 CFR 1926.752 (Revision)

Legal Deadline:

None

Abstract:

In 1992, OSHA announced that it would develop a proposal for revising steel erection safety requirements using the negotiated rulemaking process. In negotiated rulemaking, OSHA, public, industry and employee representatives meet as an advisory committee and attempt to forge a consensus on a proposed standard. An advisory committee for this rule was formed in 1994. Its work resulted in the publication of a proposed rule on August 13, 1998. The written comment period ended November 17, 1998. A public hearing was held in Washington, DC, on December 1-11, 1998. The post-hearing comment period closed April 12, 1999. OSHA is close to completing a final rule.

Statement of Need:

In 1989, the Ironworkers International Union and National Erectors Association petitioned OSHA to revise the steel erection standard through negotiated rulemaking. In light of the significant number of steel erection fatalities and injuries and concerns that the Agency's existing rule fails to adequately address a number of factors affecting safety, OSHA determined that the current rule needed to be revised.

Summary of Legal Basis:

The legal basis for the proposed steel erection rule is a preliminary finding that workers engaged in steel erection work are at significant risk of serious injury or death as a result of that work.

Alternatives:

OSHA considered continuing to rely on the existing rule. The Agency also considered issuing a proposed rule without negotiated rulemaking. Leaving the existing rule unchanged was rejected because of the apparent inadequacies of the standard. Negotiated rulemaking was chosen to help resolve conflicts and produce a proposal sooner.

Anticipated Cost and Benefits:

OSHA expects compliance with the proposal to impose annualized costs of about $50 million per year. Benefits are expected to include the prevention of about 14 fatalities and 824 lost workday injuries per year.

Risks:

OSHA estimates that at least 28 workers die each year while engaged in steel erection. Falls continue to be the leading cause of job-related deaths among construction workers, and steel erection involves a significant degree of exposure to fall hazards.

Timetable:

Action	Date	FR Cite
Notice of Committee Establishment	05/11/94	59 FR 24389
NPRM	08/13/98	63 FR 43451
NPRM Comment Period End	11/17/98	63 FR 43451
Public Hearing	12/01/98	
Final Rule	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Russell B. Swanson
Director, Directorate of Construction
Department of Labor
Occupational Safety and Health Administration
Room N3468
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-2020
Fax: 202 693-1689
Email: bswanson@dol.gov

RIN: 1218–AA65

DOL—OSHA

89. RECORDING AND REPORTING OCCUPATIONAL INJURIES AND ILLNESSES (SIMPLIFIED INJURY/ILLNESS RECORDKEEPING REQUIREMENTS)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

29 USC 657; 29 USC 673

CFR Citation:

29 CFR 1904; 29 CFR 1952.4

Legal Deadline:

None

Abstract:

OSHA requires employers to keep records of occupational illnesses and injuries. These records are used by OSHA and the Bureau of Labor Statistics (BLS), among others, to develop data on workplace safety and health by industry and across industries. Over the years concerns about the reliability and utility of these data have been raised by Congress, the National Institute for Occupational Safety and Health (NIOSH), the National Academy of Sciences, the Office of Management and Budget (OMB), the General Accounting Office, business and labor, as well as BLS and OSHA. In the late 1980s, OSHA contracted with the Keystone Center to bring together representatives of industry, labor, government, and academia in a year-long effort to discuss problems with OSHA's injury and illness recordkeeping system. Keystone issued a report with specific recommendations on how to improve the system. In 1995, OSHA held several meetings with stakeholders from business, labor and government to obtain feedback on a draft OSHA recordkeeping proposal and to gather related information.

OSHA published a Notice of Proposed Rulemaking (NPRM) in the February 2, 1996 Federal Register that contained revised recordkeeping requirements and recordkeeping forms. The original 90-day public comment period was extended another 60 days and ended July 2, 1996. During that comment period, the public submitted over 450 written comments to OSHA Docket R-02. In addition, OSHA held two public meetings in Washington, DC (March 26-29 and April 30-May 1) resulting in 1,200 pages of transcripts from nearly 60 presentations. OSHA is now planning to issue a final rule that incorporates changes based on an analysis of the public comments and testimony.

Statement of Need:

The occupational injury and illness records maintained by employers are an important component of OSHA's program. The records are used by employers and employees to identify and evaluate workplace safety and health hazards, and they provide OSHA personnel with necessary information during workplace inspections. The records also provide the source data for the Annual Survey of Occupational

Injuries and Illnesses conducted by the BLS.

All of these uses of the data are affected by the quality of the records employers maintain. Higher quality data lead to higher quality analyses, which in turn lead to better decisions about occupational safety and health matters. To improve the quality of the records and enhance the use of the information, OSHA needs to provide clearer regulatory guidance to employers and simplify the recordkeeping forms.

Summary of Legal Basis:

The legal basis for issuance of this final rule is section 8(c)(1) of the OSH Act, which requires employers to record and report such records as are necessary for the enforcement of the Act and for developing information on the causes and prevention of occupational accidents and illnesses, as required by regulation, and section 24(a) of the Act, which requires OSHA to develop an effective program of occupational safety and health statistics to further the purposes of the Act.

Alternatives:

The alternative to publication of a final rule is to take no action and continue to administer the injury and illness recordkeeping system using the current regulation, forms and guidelines. This alternative is unacceptable because it does not address the problems with the current system identified by participants in the Keystone dialogue and other OSHA stakeholders.

Anticipated Cost and Benefits:

OSHA has not determined the costs and benefits of the final rule.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	02/02/96	61 FR 4030
NPRM Comment Period End	07/02/96	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Organizations

Government Levels Affected:

None

Agency Contact:

Marthe B. Kent
Director, Directorate of Safety Standards Programs
Department of Labor
Occupational Safety and Health Administration
Room N3609
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-2222
Fax: 202 693-1663

RIN: 1218–AB24

DOL—OSHA

90. ERGONOMICS PROGRAMS: PREVENTING MUSCULOSKELETAL DISORDERS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

29 USC 651; 29 USC 652; 29 USC 655; 29 USC 657; 33 USC 941; 40 USC 333

CFR Citation:

29 CFR 1910

Legal Deadline:

None

Abstract:

Work-related musculoskeletal disorders (MSDs) are a leading cause of pain, suffering, and disability in American workplaces. Since the 1980s, the Occupational Safety and Health Administration (OSHA) has had a number of initiatives related to addressing these problems, including enforcement under the general duty clause, issuance of guidelines for the meatpacking industry, and development of other compliance-assistance materials.

The Agency decided that, given the magnitude and persistence of the problem, a regulatory approach was appropriate to ensure that the largest possible number of employers and employees become aware of the problems and ways of preventing work-related musculoskeletal disorders. OSHA has examined and analyzed the extensive scientific literature documenting the problem of work-related musculoskeletal disorders, the causes of the problem, and effective solutions; conducted a telephone survey of over 3,000 establishments regarding their practices to prevent work-related musculoskeletal disorders; and completed a number of site visits to facilities with existing programs. The Agency has also held numerous stakeholder meetings to solicit input from individuals regarding the provisions of a program standard to prevent work-related musculoskeletal disorders.

The Agency believes that the scientific evidence supports the need for a standard and that the availability of effective and reasonable means to control these hazards has been demonstrated. The Agency, therefore, issued a proposed rule for ergonomics late in 1999 and is currently working on a final rule.

Statement of Need:

OSHA estimates that work-related musculoskeletal disorders in the United States account for over 600,000 injuries and illnesses that are serious enough to result in days away from work (34 percent of all lost workday injuries reported by employers to the Bureau of Labor Statistics (BLS)). These disorders now account for one out of every three dollars spent on workers' compensation. It is estimated that employers spend as much as $15 billion a year in direct costs for MSD-related workers' compensation, and up to three to four times that much for the indirect costs of these disorders, such as those associated with hiring and training replacement workers. In addition to these monetary effects, MSDs often impose a substantial personal toll on affected workers who may no longer be able to work or perform simple personal tasks like buttoning their clothes or brushing their hair.

Scientific evidence associates MSDs with stresses to various body parts caused by the way certain tasks are performed. The positioning of the body and the type of physical work that must be done to complete a job may cause persistent pain and lead to deterioration of the affected joints, tissues, and muscles. The longer the worker must maintain a fixed or awkward posture, exert force, repeat the same movements, experience vibration, or handle heavy items, the greater the chance that such a disorder will occur. These job-related stresses are referred to as ''ergonomic risk factors,'' and the scientific literature demonstrates that exposure to these risk factors, particularly in combination, significantly increases an

employee's risk of developing a work-related musculoskeletal disorder. Jobs involving exposure to ergonomic risk factors appear in all types of industries and in all sizes of facilities.

Musculoskeletal disorders occur in all parts of the body—the upper extremity, the lower extremity, and the back. An example of the increasing magnitude of the problem involves repeated trauma to the upper extremity, or that portion of the body above the waist, in forms such as carpal tunnel syndrome and shoulder tendinitis. In industries such as meatpacking and automotive assembly, approximately 10 out of 100 workers report work-related MSDs from repeated trauma each year. The number of work-related back injuries occurring each year is even larger than the number of upper extremity disorders. Industries reporting a large number of cases of back injuries include hospitals and nursing homes.

The evidence OSHA has assembled and analyzed indicates that technologically and economically feasible measures are available to significantly reduce exposures to ergonomic risk factors and the risk of developing work-related musculoskeletal disorders. Many companies that have voluntarily implemented ergonomics programs have demonstrated that effective ergonomic interventions are available to reduce MSDs. Many of these interventions are simple and inexpensive, but nevertheless have a significant effect on the occurrence of work-related musculoskeletal disorders. Benefits include substantial savings in workers' compensation costs, increased productivity, and decreased turnover.

Summary of Legal Basis:

The legal basis for the rule is a finding by the Secretary of Labor that workers in workplaces within OSHA's jurisdiction are at significant risk of incurring work-related musculoskeletal disorders.

Alternatives:

OSHA has considered many different regulatory alternatives. These include variations in the scope of coverage, particularly with regard to industrial sectors, work processes, and degree of hazard.

Anticipated Cost and Benefits:

Implementation costs of an ergonomics program standard would include those related to identifying and correcting problem jobs using engineering and administrative controls. Benefits expected include reduced pain and suffering, both from prevented disorders as well as reduced severity in those disorders that do occur, decreased numbers of workers' compensation claims, and reduced lost work time. Secondary benefits may accrue from improved quality and productivity due to better designed work systems.

Risks:

The data OSHA has obtained and analyzed indicate that employees are at significant risk of developing or aggravating musculoskeletal disorders due to exposure to risk factors in the workplace. In addition, information from site visits, the scientific literature, the Agency's compliance experience, and other sources indicates that there are economically and technologically feasible means of addressing and reducing these risks to prevent the development or aggravation of such disorders, or to reduce their severity. These data and analyses were presented in the preamble to the proposed standard published in the Federal Register.

Timetable:

Action	Date	FR Cite
ANPRM	08/03/92	57 FR 34192
ANPRM Comment Period End	02/01/93	
SBREFA Panel	03/02/99	
NPRM	11/23/99	64 FR 65768
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Undetermined

Agency Contact:

Marthe B. Kent
Acting Director, Directorate of Health Standards Programs
Department of Labor
Occupational Safety and Health Administration
Room N3718
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-1950
Fax: 202 693-1678

RIN: 1218–AB36

DOL—OSHA

91. OCCUPATIONAL EXPOSURE TO TUBERCULOSIS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

29 USC 655(b)

CFR Citation:

29 CFR 1910.1035

Legal Deadline:

None

Abstract:

On August 25, 1993, the Labor Coalition to Fight TB in the Workplace petitioned the Occupational Safety and Health Administration (OSHA) to develop an occupational health standard to protect workers against the transmission of tuberculosis (TB). The Coalition stated that although the Centers for Disease Control and Prevention (CDC) had developed guidelines for controlling the spread of TB, many of the TB outbreak investigations conducted by CDC showed that many employers were not fully implementing the CDC guidelines. After reviewing the available information, OSHA preliminarily concluded that a significant risk of occupational transmission of TB exists for some workers in some work settings and began rulemaking on a proposed standard.

To assist in the development of the proposed standard, OSHA consulted with parties outside the Agency. The preliminary risk assessment was peer-reviewed by four experts with specific knowledge in the areas of TB disease and risk assessment. In addition, OSHA conducted stakeholder meetings with representatives of various groups that might be affected by the proposed standard. The draft proposed standard was also reviewed and commented on by affected small business entities under the Small Business Advocacy Review Panel requirements of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and by the Office of Management and Budget (OMB) under Executive Order 12866.

On October 17, 1997, OSHA published its proposed standard for occupational exposure to TB (62 FR 54160). The proposed standard would cover

workers in hospitals, nursing homes, hospices, correctional facilities, homeless shelters, and certain other work settings where workers are at significant risk of becoming infected with TB while caring for their patients or clients or performing certain procedures. The proposed standard would require employers to protect TB-exposed workers using infection control measures that have been shown to be highly effective in reducing or eliminating work-related TB infections. Such measures include procedures for early identification of individuals with infectious TB, isolation of individuals with infectious TB using appropriate ventilation, use of respiratory protection in certain situations, and skin testing and training of employees.

After the close of the written comment period for the proposed standard on February 17, 1998, informal public hearings were held in Washington, DC (April 7-17), Los Angeles, CA (May 5-7), New York City, NY (May 19-21), and Chicago, IL (June 2-4). At the end of the public hearings a post-hearing comment period was established. The post-hearing comment period closed on October 5, 1998. On June 17, 1999 OSHA reopened the rulemaking record to submit the Agency's report on homeless shelters and certain other documents that became available to the Agency after the close of the post-hearing comment period. During this limited reopening of the rulemaking record, OSHA also requested interested parties to submit comments and data on the Agency's preliminary risk assessment in order to obtain the best, most recent data for providing the most accurate estimates of the occupational risk of tuberculosis.

Statement of Need:

TB is a contagious disease caused by the bacterium Mycobacterium tuberculosis. Infection is acquired by the inhalation of airborne particles carrying the bacterium. These airborne particles, called droplet nuclei, can be generated when persons with pulmonary TB in the infectious stage of the disease cough, sneeze, or speak. In some individuals who inhale the droplet nuclei, TB bacteria establish an infection. In most cases, the bacteria are contained by the individual's immune system. However, in some cases, the bacteria are not contained by the immune system and continue to grow and invade the tissue, leading to the progressive destruction of the organ involved. In most cases, this organ is the lung, although other organs may also become infected.

From 1953, when active cases began to be reported in the United States, until 1984, the number of annual reported cases declined 74 percent, from 84,304 cases to 22,255 cases. However, this steady decline did not continue. Instead, from 1985 to 1992, the number of reported cases increased 20.1 percent. TB control efforts were re-initiated in some areas of the country and from 1993 to 1998, the number of cases in the United States again declined. A large portion of the decrease occurred in high incidence areas, such as New York City, where intervention efforts were focused. However, despite the recent decrease in active cases, there were still 18,371 reported TB cases in 1998. Outbreaks of TB continue to occur and multidrug-resistant forms of TB disease continue to spread to new States. In addition, more than 10 to 15 million persons in the United States have latent TB infection and are at risk of developing TB disease sometime in the future. Moreover, the factors that led to the resurgence from 1985 to 1992 (e.g., increases in homelessness, HIV infection, immigration from countries with high rates of infection) still exist.

Providing health care for individuals with TB increases the risk of occupational exposure among healthcare workers. Many of the outbreaks of TB have occurred in health care facilities, resulting in the transmission of TB to both patients and health care workers. CDC found that the factors contributing to these outbreaks included delayed diagnosis of TB, delayed initiation of effective therapy, delayed initiation and inadequate duration of TB isolation, inadequate ventilation of isolation rooms, lapses in TB isolation practices, and lack of adequate respiratory protection. CDC analyzed data from several of the outbreaks and found that the transmission of TB decreased significantly when recommended TB control measures were implemented. Workers outside health care also provide services to patient or client populations that have an increased rate of TB disease. For example, occupational transmission of TB has been documented in correctional facilities, and the standard would cover such workers.

Summary of Legal Basis:

The legal basis for the proposed TB standard is a preliminary finding by the Secretary of Labor that workers in hospitals, nursing homes, hospices, correctional facilities, homeless shelters, and certain other work settings are at a significant risk of incurring TB infection while caring for their patients and clients or performing certain procedures.

Alternatives:

Prior to a decision to publish a proposal, OSHA considered a number of options, including whether or not to develop an emergency temporary standard, publish an advance notice of proposed rulemaking, or to enforce existing regulations.

Anticipated Cost and Benefits:

Costs will be incurred by employers for engineering controls, respiratory protection, medical surveillance, training, exposure control, recordkeeping, and work practice controls. Benefits will include the prevention of work-related TB transmissions and infections, and a corresponding reduced risk of exposure among the general population. OSHA estimates that more than 5 million workers are exposed to TB in the course of their work. The Agency estimates that the proposed provisions will result in annual costs of $245 million. Implementation of the standard is estimated to reduce the number of work-related cases of TB by 70 to 90 percent in the work settings covered, thus preventing approximately 21,400 to 25,800 work-related infections per year, 1,500 to 1,700 active cases of TB resulting from these infections, and approximately 115 to 136 deaths resulting from these active cases.

Risks:

From 1985 to 1992, the number of reported cases of TB in the United States increased, reversing a previous 30-year downward trend. While there has been a recent decrease in the reported number of cases of TB in the general population, a large part of this decrease can be attributed to focused intervention efforts in areas of high incidence of TB. Fourteen states showed an increase or no change in the number of reported cases in 1998, and the factors that contributed to the resurgence continue to exist, along with exposure of certain workers to patient or client populations with an increased rate of TB. In addition, TB outbreaks continue to occur and multidrug-resistant strains of TB continue to spread to new States. Therefore, employees in work settings such as health care or correctional facilities, who have contact with infectious individuals, are at high risk of occupational transmission of TB. OSHA estimates that the average lifetime

occupational risk of TB infection ranges from 30 to 386 infections per 1000 workers exposed to TB on the job and that the average lifetime occupational risk of TB disease ranges from 3 to 39 cases of active TB disease per 1000 workers exposed to TB. Active disease can cause signs and symptoms such as fatigue, weight loss, fever, night sweats, loss of appetite, persistent cough, and shortness of breath, and may result in serious respiratory illness or death.

Timetable:

Action	Date	FR Cite
SBREFA Panel	09/10/96	
NPRM	10/17/97	62 FR 54160
NPRM Comment Period End	02/17/98	
Post Hearing Comment End	10/05/98	
Record Reopening	06/17/99	64 FR 32447
Second Reopening Comment Period End	06/28/99	64 FR 34625
Reopening Comment Period End	08/02/99	
Final Rule	04/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

During this rulemaking, OSHA met with small business stakeholders to discuss their concerns, and conducted an initial Regulatory Flexibility Analysis to identify any significant impacts on a substantial number of small entities. In addition, OSHA conducted a special study of homeless shelters and set aside certain hearing dates for persons who wished to testify on homeless shelter issues.

Agency Contact:

Marthe B. Kent
Acting Director, Directorate of Health Standards Programs
Department of Labor
Occupational Safety and Health Administration
Room N3718
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-1950
Fax: 202 693-1678

RIN: 1218–AB46

DOL—OSHA

92. EMPLOYER PAYMENT FOR PERSONAL PROTECTIVE EQUIPMENT

Priority:

Other Significant

Legal Authority:

29 USC 655(b); 29 USC 657; 33 USC 941; 40 USC 333

CFR Citation:

29 CFR 1910.132; 29 CFR 1915.152; 29 CFR 1917.96; 29 CFR 1918.106; 29 CFR 1926.95

Legal Deadline:

None

Abstract:

Generally, OSHA standards require that protective equipment (including personal protective equipment (PPE)) be provided and used when necessary to protect employees from hazards that can cause them injury, illness, or physical harm. In this discussion, OSHA uses the abbreviation ''PPE'' to cover both personal protective equipment and other protective equipment. The Agency has proposed to revise its PPE standards to clarify who is required to pay for required PPE and under what circumstances. According to the proposal, employers would be required to provide all OSHA-required PPE at no cost to employees, with the following exceptions: the employer would not need to pay for safety-toe protective footwear or prescription safety eyewear if all three of the following conditions are met: (1) The employer permits such footwear or eyewear to be worn off the job-site; (2) the footwear or eyewear is not used in a manner that renders it unsafe for use off the job-site (for example, contaminated safety-toe footwear would not be permitted to be worn off a job-site); and (3) such footwear or eyewear is not designed for special use on the job. Employers are also not required to pay for the logging boots required by 29 CFR 1910.266(d)(1)(v).

Statement of Need:

The regulatory language used in OSHA standards has generally clearly stated that the employer must provide PPE and ensure that employees wear it. However, the regulatory language regarding the employer's obligation to pay for the PPE has varied.

OSHA attempted to clarify its position on the issue of payment for required PPE in a compliance memorandum to its field staff dated October 18, 1994. The memorandum stated that it was the employer's obligation to provide and pay for PPE except in limited situations.

Recently, the Occupational Safety and Health Review Commission declined to accept this interpretation (Secretary of Labor v. Union Tank Car, OSHRC No. 96-0563). The Commission vacated a citation against an employer who failed to pay for OSHA-required PPE, finding that the Secretary had failed to adequately explain the policy outlined in the 1994 memorandum in light of several inconsistent earlier letters of interpretation from OSHA. Therefore, the Agency needs to clarify who is to pay for PPE under what conditions.

Summary of Legal Basis:

The legal basis for this proposed rule is the need to clarify OSHA's intent with regard to the payment for protective equipment required by OSHA standards.

Alternatives:

OSHA has considered several alternative approaches to resolving this issue, including leaving this as a labor-management issue, issuing compliance directives to identify what PPE the employer must pay for, or requiring the employer to pay for all PPE. OSHA believes that, in this case, revising the standard to clarify who is to pay for the PPE is the most appropriate way to proceed. It is the only approach that will assure significant public participation in the resolution of this issue, and the codification of that resolution.

Anticipated Cost and Benefits:

It is estimated that the proposed rule will shift, at most, annualized costs to employers of no more than $62 million across all affected industries. It is also estimated that the proposed rule will prevent over 47,000 injuries and seven fatalities that occur annually as a result of the non-use or misuse of personal protective equipment by employees required to pay for their own PPE.

Risks:

Substantive requirements for protective equipment are included in other OSHA standards. This proposed rule is designed solely to clarify OSHA's intent as to what protective equipment must be paid for by the employer. Accordingly, no assessment of risk is required.

Timetable:

Action	Date	FR Cite
NPRM	03/30/99	64 FR 15401
NPRM Comment Period End	06/14/99	64 FR 15401
Informal Public Hearing End	08/13/99	
Final Rule	04/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

State, Local, Federal

Agency Contact:

Marthe B. Kent
Director, Directorate of Safety Standards Programs
Department of Labor
Occupational Safety and Health Administration
Room N3609
200 Constitution Avenue NW
FP Building
Washington, DC 20210
Phone: 202 693-2222
Fax: 202 693-1663

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DEPARTMENT OF TRANSPORTATION (DOT)

Statement of Regulatory Priorities

The Department of Transportation (DOT) consists of ten operating administrations, the Bureau of Transportation Statistics and the Office of the Secretary, each of which has statutory responsibility for a wide range of regulations. For example, DOT regulates safety in the aviation, motor carrier, railroad, mass transit, motor vehicle, maritime, commercial space, and pipeline transportation areas. DOT regulates aviation consumer and economic issues and provides financial assistance and writes the necessary implementing rules for programs involving highways, airports, mass transit, the maritime industry, railroads, and motor vehicle safety. It writes regulations carrying out such disparate statutes as the Americans with Disabilities Act and the Uniform Time Act. It regulates the construction and operation of bridges over navigable waters, the prevention of oil pollution, and the security of commercial aviation and passenger vessels. Finally, DOT has responsibility for developing policies that implement a wide range of regulations that govern internal programs such as acquisition and grants, access for the disabled, environmental protection, energy conservation, information technology, property asset management, seismic safety, security, and the use of aircraft and vehicles.

Although it carries this heavy regulatory workload, the Department has long been recognized as a leader in Federal efforts to improve and streamline the regulatory process and ensure that regulations do not impose unnecessary burdens. The Department's regulatory policies and procedures provide a comprehensive internal management and review process for new and existing regulations and ensure that the Secretary and other appropriate appointed officials review and concur in all significant DOT rules.

The Department has adopted a regulatory philosophy that applies to all its rulemaking activities. This philosophy is articulated as follows: DOT regulations must be clear, simple, timely, fair, reasonable, and necessary. They will be issued only after an appropriate opportunity for public comment, which must provide an equal chance for all affected interests to participate, and after appropriate consultation with other governmental entities. The Department will fully consider the comments received. It will assess the risks addressed by the rules and their costs and benefits, including the cumulative effects. The Department will consider appropriate alternatives, including nonregulatory approaches. It will also make every effort to ensure that legislation does not impose unreasonable mandates.

DOT continually seeks to improve its regulatory process. The Department's creation of an electronic, Internet-accessible docket that can also be used to submit comments electronically; the use of direct final rulemaking; and the use of regulatory negotiation are three examples of this.

The Department has engaged in a wide variety of activities to help cement the partnerships between its agencies and its customers that will produce good results for transportation programs and safety. These have included summits with front-line regulators and representatives of regulated industries. In addition, the Department's agencies have established a number of continuing partnership mechanisms in the form of rulemaking advisory committees.

Throughout the Department, we are also actively engaged in the review of existing rules to determine whether they need to be revised or revoked. These reviews are in accordance with section 610 of the Regulatory Flexibility Act, the Department's regulatory policies and procedures, Executive Order 12866, and/or the President's directive to ''consider writing existing regulations in plain language....'' Appendix D to our Regulatory Agenda highlights our efforts in this area.

Office of the Secretary of Transportation (OST)

The Office of the Secretary (OST) oversees the regulatory process for the Department. OST implements the Department's regulatory policies and procedures and is responsible for ensuring the involvement of top management in regulatory decisionmaking. Through the General Counsel's office, OST is also responsible for ensuring that the Department complies with Executive Order 12866 and other legal and policy requirements affecting rulemaking, including a number of new statutes and Executive orders. Although OST's principal role concerns the review of the Department's significant rulemakings, this office also plays an important role in the substance of projects concerning aviation economic rules and those affecting the various elements of the Department.

OST provides guidance and training regarding compliance with regulatory requirements and process for use by personnel throughout the Department. OST also plays an instrumental part in the Department's efforts to improve our economic analyses, risk assessment, and regulatory flexibility analyses. In addition, OST has a leadership role in implementing the President's plain language initiatives.

OST also leads and coordinates the Department's response to Administration and congressional proposals that concern the regulatory process. The General Counsel's Office works closely with representatives of other agencies, the Office of Management and Budget, the White House, and congressional staff to provide information on how various proposals would affect the ability of the Department to perform its safety, infrastructure, and other missions.

OST is continually incorporating new technology into its rulemaking process through the docket management system (DMS). The DMS stores electronic images in unalterable form. It includes all rulemaking and support documents, public comments, and other documents included in the public docket. This electronic docket is accessible via the Internet, and now accepts electronic filing of comments. OST and the General Counsel's Office includes hyperlinks to other useful DOT regulatory web sites, including the public rulemaking dockets, and contacts for many issues of special interest to the public (http://regs.dot.gov/).

United States Coast Guard (USCG)

The United States Coast Guard's statutory responsibilities include protecting the marine environment; enforcing U.S. laws and international treaties; performing search and rescue; and ensuring marine safety and security.

The majority of the regulatory actions issued by the Coast Guard are classified as routine and frequent because they take effect for a limited time and at specific locations. These temporary actions allow local Coast Guard units to ensure safety during marine events. The Coast Guard issues approximately 30 regulations annually that set national standards or respond to specific statutory mandates. The Marine Safety Council, a board of senior Coast Guard Leaders, approves each of these rulemaking projects, monitors the Coast Guard's regulatory program, and advises the Commandant on regulatory matters. The following are significant aspects of the Coast Guard's regulatory program:

- The Coast Guard is an active member of the Vice President's Plain Language

Action Network. It has used plain language, including question/answer format to issue rules directly affecting the public, such as raising the threshold of property damage for reports of accidents involving recreational vessels. The Coast Guard issues all new regulations and revisions to whole parts of the CFR in plain language to meet the Presidential Memorandum on Plain Language. Plain language updates will be an important part of the Coast Guard's review of all regulations under the Regulatory Flexibility Act.

- The Coast Guard encourages early public involvement in rulemaking through a variety of public meetings and the ongoing work of ten advisory committees. In addition, public comments are requested on existing rules identified for analysis each year and identified in Appendix D of the fall agenda.
- Recognizing that it should issue only necessary regulations tailored to impose the least burden on society, the Coast Guard has developed a broad Prevention Through People Program, which develops and encourages a wide variety of voluntary actions by industry and individuals to improve marine safety. To support this effort, the Coast Guard has several Quality Partnerships.
- Finally, to ensure that all regulations are necessary, each agenda item specifies how it supports at least one of the goals of the Coast Guard's Strategic Plan. Strategic goals include maritime safety, protection of natural resources, maritime security, maritime mobility, and national defense.

Federal Aviation Administration (FAA)

The FAA issues regulations to provide a safe, secure, and efficient global aviation system for civil aircraft.

In response to the June 1, 1998, Presidential Memorandum regarding the use of plain language in regulations, the FAA re-examined the use of plain language in regulations. The result of this review was revisions to 14 CFR Part 11, which delineates the process for rulemaking changes. This rulemaking effort is only the first of several planned revisions to make the regulations more concise and easier to understand. Other actions include:

- Supporting the FAA's Safety Agenda on Safer Skies. This agenda is based on a comprehensive review of the causes of aviation accidents and is designed to bring about a five-fold (80 percent) reduction in fatal accidents. The reformed rulemaking process supports this agenda by ensuring that appropriate resources are available to support those rulemaking projects identified as the agency's highest priority. Projects related to controlled flight into terrain, loss of control of an aircraft, uncontained engine failures, runway incursions, weather, pilot decisionmaking, and cabin safety are some of the focus areas identified that may result in rulemaking, advisory and guidance materials.
- Continuing to involve the aviation community early in the regulatory process. The FAA obtains input, both on the rule and the economics, from affected parties prior to publishing a proposed regulation by using the Aviation Rulemaking Advisory Committee, which represents members from all aviation interests. It is presently working on the resolution of more than 70 issues. In 1999, the ARAC submitted recommendations on more than 35 rulemaking documents.
- Continuing to harmonize the U.S. aviation regulations with those of other countries. The harmonization of the U.S. regulations with the European Joint Aviation Regulations (JAR) is the FAA's most comprehensive long-term rulemaking effort. The differences worldwide in certification standards, practices and procedures, and operating rules must be identified and minimized to reduce the regulatory burden on the international aviation system. The differences between the FAA regulations and the requirements of other nations impose a heavy burden on U.S. aircraft manufacturers and operators. Harmonization and standardization should help the U.S. aerospace industry remain internationally competitive. While the overall effort to achieve this is global, it will be accomplished by many small, individual, nonsignificant rulemaking projects. The ARAC completed more than 90 reports that will lead to harmonizing FAA and JAA certification regulations.
- Implementing the recommendations of the White House Commission on Aviation Safety and Security. FAA rulemaking actions are continuing in the areas of: 1) revising repair station requirements; and 2) improving security of checked baggage on flights within the United States.
- Continuing to recognize the needs of small entities by complying with the Small Business Regulatory Enforcement Fairness Act and addressing small entity concerns whenever appropriate in rulemaking documents. In response to the Act, the FAA has established a Small Entity Contact, a web site on FAA's home page, a toll free number, and an e-mail address for receipt of inquiries.
- Ensuring that the congressional mandates for rulemaking deadlines established by the FAA Reauthorization Act of 1996 are met. One mandate is the issuance of a final rule 16 months after the close of the comment period on the proposed rule.

Top regulatory priorities for 2000-2001 include a duty limitations and rest requirements rule to ensure that pilots are sufficiently rested for duty, certification of airports, and a flight operational quality assurance program proposal to allow for the voluntary disclosure of operational safety information.

Federal Highway Administration (FHWA)

The FHWA anticipates that its priority for fiscal year 2001 will be continuing implementation of the Transportation Equity Act for the 21st Century (TEA-21), which reauthorizes the surface transportation programs administered by the FHWA. The FHWA will continue to implement this legislation in the least burdensome and restrictive way possible consistent with the FHWA's mission. The FHWA will also pursue regulatory reform in areas where project development can be streamlined or accelerated, duplicative requirements can be consolidated, recordkeeping requirements can be reduced or simplified, and the decisionmaking authority of our State and local partners can be increased.

An example of this reform can be found in the FHWA's issuance of notices of proposed rulemaking for National Environmental Policy Act (NEPA) and Related Procedures for Transportation Decisionmaking and Statewide Metropolitan Planning.

Federal Motor Carrier Safety Administration (FMCSA)

The FMCSA is the newest agency in the Department of Transportation. It was established on January 1, 2000 by the Motor Carrier Safety Improvement Act of 1999 (MCSIA) (Pub. L.106-159). As required by MCSIA, FMCSA has developed a strong Safety Action Plan to guide it towards the goal of reducing the number of fatalities resulting from crashes involving large trucks by 50 percent from the 1998 baseline by the year 2010. Setting new performance standards for vehicles, drivers, and motor carriers through regulation will

raise the bar for safety in commercial operations. The FMCSA now is responsible for most of the functions of the former Office of Motor Carriers in the Federal Highway Administration. These include the reform of hours-of-service requirements and the longstanding zero-based review of the Federal Motor Carrier Safety Regulations. Other regulatory initiatives are required by MCSIA. Over the next year, the new FMCSA is committed to developing an effective and efficient regulatory program that meets the expectations of Congress, its stakeholders and partners, and the general public. This will assist the new agency in meeting one of the stated goals of MCSIA to reduce the number and severity of large-truck involved crashes through expedited completion of rulemaking proceedings.

National Highway Traffic Safety Administration (NHTSA)

The statutory responsibilities of the National Highway Traffic Safety Administration (NHTSA) relating to motor vehicles include reducing the number of and mitigating the effects of motor vehicle crashes and related fatalities and injuries, providing motor vehicle information to consumers, and improving automotive fuel efficiency. NHTSA pursues policies that encourage the development of nonregulatory approaches when feasible in meeting its statutory mandates. It issues new standards and regulations or amendments to existing standards and regulations when appropriate. It ensures that regulatory alternatives reflect a careful assessment of the problem and a comprehensive analysis of the benefits, costs, and other impacts associated with the proposed regulatory action. Finally, it considers alternatives consistent with the Administration's regulatory principles.

In addition to numerous programs that focus on the safety and performance of the motor vehicle, the Agency is engaged in a variety of programs to improve driver behavior. These programs emphasize the human aspects of motor vehicle safety and recognize the important role of the States in this common pursuit. This goal is accomplished through a number of means, including encouraging initiatives in such areas as safety belt use, child safety-seat use, activities aimed at combating impaired driving and aggressive driving, and consumer information activities.

NHTSA is conducting several program evaluations that are designed to review and evaluate the actual benefits, costs, and overall effectiveness of existing standards and regulations. For example, it will continue evaluating Standard 208's new measures to improve the safety performance of air bags, Standard 214's dynamic side-impact requirements, and Standard 108's requirement for reflective marking on heavy truck trailers to enhance their detection at night or under other conditions of reduced visibility. NHTSA will continue evaluating the implementation of the American Automobile Labeling Act, which requires new passenger cars, pickup trucks, vans, and sport utility vehicles to carry labels providing information on their domestic and foreign parts content. It is also evaluating the efficacy of child safety seat registration for increasing consumer response to recalls of defective seats. NHTSA is starting two evaluations of safety equipment for heavy trucks and tractor trailers: antilock brake systems (Standard 121) and rear impact guards (Standards 223 and 224).

NHTSA's regulatory program includes additional proposals that will be undertaken in order to allow design flexibility, promote new technology, and encourage market competition and consumer choice.

Federal Railroad Administration (FRA)

The Federal Railroad Administration (FRA) exercises regulatory authority over all areas of railroad safety.

Fashioning regulations that have favorable benefit-to-cost ratios, and that where feasible, incorporate flexible performance standards, requires cooperative action by all affected parties. In order to foster an environment of collaborative rulemaking, FRA established the Railroad Safety Advisory Committee (RSAC). The purpose of RSAC is to develop consensus recommendations for regulatory action on issues referred to it by FRA. Where consensus is achieved, and FRA believes it serves the public interest, the resulting rule is very likely to be better understood, more widely accepted, more cost-beneficial, and more correctly applied. Where consensus cannot be achieved, however, FRA will fulfill its regulatory role without the benefit of RSAC's recommendations.

The RSAC has met on a quarterly basis so far and currently has working groups addressing the following tasks: 1) The development of regulations governing track and railroad maintenance equipment; 2) the review of FRA regulations for their applicability to historic railroads; 3) the development of safety standards for locomotive crashworthiness; 4) the development of safety standards for locomotive working conditions; 5) the development of locomotive event recorder accident survivability standards; 6) the development of regulations governing the use of positive train control (PTC) systems; 7) the development of a new accident reporting threshold; and 8) revision of regulations governing the use of utility employees.

In addition to RSAC, FRA continues to use collaborative rulemaking to address passenger safety issues. FRA established a working group to address Passenger Equipment Safety Standards and published a final rule in the first phase of this rulemaking initiative in May 1999 based on its recommendations. FRA continues to conduct research related to the second phase of the rule, and expects to reconvene the working group on Passenger Equipment Safety Standards in late 2000. FRA also engaged in extensive public outreach to develop regulations regarding the use of train whistles, and published an NPRM in January 2000.

Federal Transit Administration (FTA)

The Federal Transit Administration (FTA) provides financial assistance to State and local governments for mass transportation purposes. The regulatory activity of FTA focuses on establishing the terms and conditions of Federal financial assistance available under the Federal transit laws.

FTA's policy regarding regulations is to:

- Implement statutory authorities in ways that provide the maximum net benefits to society;
- Keep paperwork requirements to a minimum;
- Allow for as much local flexibility and discretion as is possible within the law;
- Ensure the most productive use of limited Federal resources;
- Protect the Federal interest in local investments; and
- Incorporate good management principles into the grant management process.

As mass transportation needs have changed over the years, so have the requirements for Federal financial assistance under the Federal transit laws and related statutes. FTA's regulatory priorities for 2000-2001 are to continue to issue rulemakings required under the

Transportation Equity Act for the 21st Century (TEA-21), to amend existing regulations as needed, and to update existing regulations for plain language.

Of particular importance to FTA is the publication of the Major Capital Investment Projects (New Starts) rule which is required by TEA-21 and will detail how the agency will evaluate and rate proposed transit projects as ''recommended,'' ''highly recommended'' or ''not recommended.'' FTA will use these ratings to recommend to Congress which of the more than 190 projects authorized in TEA-21 should be federally funded.

TEA-21 also requires that FTA and FHWA amend the joint Environmental and Statewide and Metropolitan Transportation Planning rules which will be of significant interest to States, transit agencies, local governmental bodies, and environmental groups.

The proposed planning rules included provisions for achieving consistency with Intelligent Transportation Systems (ITS) projects and the National ITS architecture and approved standards.

In addition FTA will issue a third-party procurement rule. FTA had previously issued guidance on the subject in the form of a FTA circular. Recipients of FTA funding followed the circular, but as a guidance document, the circular did not have the force and effect of law. The proposed rule will correct that problem

Maritime Administration (MARAD)

MARAD administers Federal laws and programs designed to promote and maintain an U.S. merchant marine capable of meeting the Nation's shipping needs for both national security and domestic and foreign commerce.

MARAD's regulatory objectives and priorities reflect the Agency's responsibility of ensuring the availability of adequate and efficient water transportation services for American shippers and consumers. To advance these objectives, MARAD issues regulations, which are principally administrative and interpretive in nature, when appropriate, in order to provide a net benefit to the U.S. maritime industry.

MARAD's regulatory priorities are to update existing regulations and to reduce unnecessary burden on the public. For example, MARAD remains committed to updating and streamlining existing regulations and administrative practices governing the following areas: 1) the ship financing guarantee process; 2) standards for evaluation and approval of applications; and 3) the process and documentation for closing of commitments to guarantee obligations issued under these regulations.

Research and Special Programs Administration (RSPA)

The Research and Special Programs Administration (RSPA) has responsibility for rulemaking under two programs. Through the Associate Administrator for Hazardous Materials Safety, RSPA administers regulatory programs under Federal hazardous materials transportation law and the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990. Through the Associate Administrator for Pipeline Safety, RSPA administers regulatory programs under the Federal pipeline safety laws and the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990.

In the area of hazardous materials transportation, the regulatory priority is to clarify through rulemaking the applicability of regulations to the loading, unloading, and storage of hazardous materials incidental to their movement in commerce. Clarifying the applicability of the regulations will facilitate compliance with them and also clarify when other requirements of Federal, State, local, and tribal governments apply.

The regulatory priority for gas and hazardous liquid pipeline transportation is to improve safety and environmental protection by managing the risks inherent in pipeline transportation. The key regulatory initiatives are to require pipelines to develop integrity management programs to validate pipe integrity of pipelines in high-density population areas, waters where currently commercial navigation exists, and areas unusually sensitive to environmental damage. Specific regulatory actions to implement this risk-based strategy in high-consequence areas include definition of areas unusually sensitive to environmental damage in the event of a pipeline rupture and integrity management rules requiring increased inspection, evaluation, and interventions to prevent and mitigate pipeline leaks.

Bureau of Transportation Statistics (BTS)

The Bureau of Transportation Statistics (BTS) is responsible for collecting, compiling, analyzing, and making accessible information on the Nation's transportation systems; identifying needs for new information and analysis and implementing programs to meet those needs; and enhancing the quality and effectiveness of the Department's statistical programs through research, the development of guidelines, coordination with related information-gathering activities conducted by other Federal agencies, and the promotion of improvements in data acquisition, archiving, dissemination, and use.

BTS's Office of Airline Information (OAI), collects airline financial and operating statistical data, covering both passenger and cargo traffic. This information gives the Government consistent and comprehensive economic and market data on individual airline operations and is used, for instance, in supporting policy initiatives, negotiating international bilateral aviation agreements, awarding international route authorities, and meeting international treaty obligations. The aviation, travel, and tourism communities value this information for a variety of purposes, such as conducting analyses of on-time performance, denied boardings, market trends, and economic analyses.

BTS's long-range regulatory priority in the aviation area is to conduct a complete review and modernization of the Passenger Origin and Destination Survey. BTS can make significant improvements by providing data to meet the needs of DOT and other users in a way that takes advantage of the information revolution and matches the dramatically changing airline industry.

BTS, in conjunction with the Office of the Secretary, is in the process of performing a zero-base review of the financial and traffic data to determine what, if any, revisions can be made to the current data collections to ensure that these collections fully support the Department's mandated aviation responsibilities. Moreover, the review will seek to identify potential savings to the affected air carriers and the Government that can be accomplished through the application of advanced information technologies to the collection, processing, validation, and dissemination of aviation data. BTS's review and modernization of the Passenger Origin and Destination Survey will be incorporated as part of this zero-base review.

Saint Lawrence Seaway Development Corporation (SLSDC)

The Saint Lawrence Seaway Development Corporation (SLSDC) is a wholly owned Government corporation

created by Congress in 1954. The primary operating service of the SLSDC is to ensure the safe transit of commercial and noncommercial vessels through the two U.S. locks and navigation channels of the Saint Lawrence Seaway System. The SLSDC works jointly with its Canadian counterpart to operate and maintain this deep draft waterway between the Great Lakes and the Atlantic Ocean. The SLSDC also works jointly with its Canadian counterpart on all matters related to rules and regulations, overall operations, vessel inspection, traffic control, navigation aids, safety, operating dates, and trade development programs.

The regulatory priority of the SLSDC is to provide its customers with the safest, most reliable, and most efficient Seaway System possible.

DOT—U.S. Coast Guard (USCG)

PROPOSED RULE STAGE

93. +MARINE TRANSPORTATION-RELATED FACILITY RESPONSE PLANS FOR HAZARDOUS SUBSTANCES (USCG-1999-5705)

Priority:

Other Significant

Legal Authority:

33 USC 1321(j); PL 101-380

CFR Citation:

33 CFR 154

Legal Deadline:

None

Abstract:

This project would implement provisions of the Oil Pollution Act of 1990 that require an owner or operator of a marine transportation-related facility transferring bulk hazardous substances to develop and operate in accordance with an approved response plan. The regulations would apply to marine transportation-related facilities that, because of their location, could cause harm to the environment by discharging a hazardous substance into or on the navigable waters or adjoining shoreline. A separate rulemaking, under RIN 2115-AE88, was developed in tandem with this rulemaking and addresses hazardous substances response plan requirements for tank vessels. This project supports the Coast Guard's strategic goals of maritime safety and protection of natural resources by reducing the amount of chemicals entering the environment, as well as reducing the consequence of pollution incidents. This action is considered significant because of substantial public and industry interest.

Statement of Need:

This rulemaking is intended to reduce the impact from hazardous substance spills from vessels and marine transportation-related facilities.

Summary of Legal Basis:

Section 4202(a) of the Oil Pollution Act of 1990 (OPA 90), codified at 33 U.S.C. 1321(j)(5), mandates that the President issue regulations requiring the preparation of oil and hazardous substance discharge response plans. Although section 4202(b)(4) of OPA 90 established an implementation schedule for these response plans for oil, it did not establish a deadline for submission or approval of hazardous substances response plans. The Coast Guard has issued separate final rules governing response plan requirements for vessels carrying oil in bulk as cargo and facilities that handle, store, or transport oil in bulk. Under 33 U.S.C. 1321, ''hazardous substances'' are designated by the Administrator of the Environmental Protection Agency. The Administrator has designated 297 chemicals as hazardous substances under this section. The Coast Guard has identified 82 hazardous substances currently carried in bulk by vessels, and transferred to or from marine transportation-related facilities.

Alternatives:

The Coast Guard intends to determine what types of response strategies would be required to address spills of different types of hazardous substances. For some substances, containment and recovery may be the appropriate response. However, some of the spilled substances may not be recoverable from the water and other actions may be necessary. Plans would be required, by statute, to address responses to a ''worst case discharge.'' For facilities, a ''worst case discharge'' is ''the largest foreseeable discharge in adverse weather conditions.''

Anticipated Cost and Benefits:

The potential costs of this rulemaking may include the costs of developing and implementing a hazardous substance response plan, maintaining contracts for response resources, reviewing and updating hazardous substance response plans, maintaining any required equipment, and training and exercising response personnel. Potential benefits include reduced risk of human exposure and enhanced environmental quality from improved ability to respond to, contain, and recover spilled hazardous substances. The analysis indicates that this project will not be economically significant. A regulatory assessment addressing costs and benefits of this rule is available in the public docket.

Risks:

Response plans are required by statute. A response plan will not prevent a discharge of a hazardous substance, but it may improve the response and help to minimize personal injury and damage to the environment. This rule should not affect the economic viability of facilities involved in transferring hazardous substances in bulk or have a significant impact on the volume of hazardous substances shipped by marine transportation-related facilities. Most facilities involved in transferring hazardous substances in bulk have developed plans, but there have not been requirements for standardization.

Timetable:

Action	Date	FR Cite
ANPRM	05/03/96	61 FR 20084
Notice of Public Hearings	07/03/96	61 FR 34775
ANPRM Comment Period End	09/03/96	
NPRM	03/31/00	65 FR 17416
NPRM Comment Period End	06/29/00	
Final Rule	04/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

Public hearings regarding this rulemaking were held in Washington, DC, on July 30, 1996; Houston, TX, on August 5, 1996; and Houston, TX, on February 26 and 27, 1997. Public meetings for the NPRM were held in New Orleans, LA, on May 10 and 11, 2000.

Agency Contact:

LT Michael Roldan
Project Manager, G-MSO
Department of Transportation
U.S. Coast Guard
2100 Second St. SW.
Washington, DC 20593-0001
Phone: 202 267-0106

RIN: 2115–AE87

DOT—USCG

94. +TANK VESSEL RESPONSE PLANS FOR HAZARDOUS SUBSTANCES (USCG-1998-4354)

Priority:

Other Significant

Legal Authority:

33 USC 1231; 33 USC 1321(j); PL 101-380

CFR Citation:

33 CFR 155

Legal Deadline:

None

Abstract:

This project would implement provisions of the Oil Pollution Act of 1990 that require an owner or operator of a tank vessel carrying bulk hazardous substances to develop and operate in accordance with an approved response plan. The regulations would apply to vessels operating on the navigable waters or within the Exclusive Economic Zone (EEZ) of the U.S. that carry bulk hazardous substances. A separate rulemaking under RIN 2115-AE87 would address hazardous substances response plan requirements for marine transportation-related facilities. This project supports the Coast Guard's strategic goals of maritime safety and protection of natural resources by reducing the amount of chemicals entering the environment, as well as reducing the consequences of pollution incidents. This project is considered significant because of substantial public and industry interest.

Statement of Need:

This rulemaking is intended to reduce the impact from hazardous substance spills from vessels.

Summary of Legal Basis:

Section 4202(a) of the Oil Pollution Act of 1990 (OPA 90), codified at 33 U.S.C. 1321(j)(5), mandates that the President issue regulations requiring the preparation of oil and hazardous substance discharge response plans. Although 4202(b)(4) of OPA 90 established an implementation schedule for these response plans for oil, it did not establish a deadline for submission or approval of hazardous substances response plans. The Coast Guard has issued separate final rules governing response plan requirements for vessels carrying oil in bulk as cargo and facilities that handle, store, or transport oil in bulk. Under section 1321, ''hazardous substances'' are designated by the Administrator of the Environmental Protection Agency. The Administrator has designated 297 chemicals as hazardous substances under this section. The Coast Guard has identified 82 hazardous substances currently carried in bulk by vessels.

Alternatives:

The Coast Guard intends to determine what types of response strategies would be required to address spills of different types of hazardous substances. For some substances, containment and recovery may be the appropriate response. However, some spilled substances may not be recoverable from the water and other actions may be necessary. Plans would be required, by statute, to address responses to a ''worst case discharge.'' For vessels, a ''worst case discharge'' is ''a discharge in adverse weather conditions of its entire cargo.''

Anticipated Cost and Benefits:

The potential costs of this rulemaking may include the costs of developing and implementing a hazardous substance response plan, maintaining contracts for spill-response resources, reviewing and updating hazardous substance response plans, maintaining any required equipment, and training and exercising response personnel. Potential benefits include reduced risk to human health, enhanced environmental quality from improved ability to respond to, contain, and recover spilled hazardous substances and a reduction in the severity of the impact of accidental hazardous substance discharges. A regulatory assessment addressing costs and benefits of this rule is available in the public docket.

Risks:

Response plans are required by statute. A response plan will not prevent a discharge of a hazardous substance, but it may improve the response and help to minimize personal injury and damage to the environment. This rule should not affect the economic viability of vessels involved in transferring hazardous substances in bulk, or have a significant impact on the volume of hazardous substances shipped by vessel. Most vessels carrying hazardous substances in bulk have developed response plans, but there have not been requirements for standardization.

Timetable:

Action	Date	FR Cite
ANPRM	05/03/96	61 FR 20084
Notice of Public Hearings	07/03/96	61 FR 34775
ANPRM Comment Period End	09/03/96	
NPRM	03/22/99	64 FR 13734
Notice of Public Hearing	06/15/99	64 FR 31994
NPRM Comment Period Extended	06/15/99	64 FR 31994
NPRM Comment Period End	06/21/99	
NPRM Extended Comment Period End	08/30/99	
Final Rule	04/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

A public hearing on this rulemaking was held in Houston, TX, on August 12 and 13, 1999.

Agency Contact:

LT Michael Roldan
Project Manager, G-MSO
Department of Transportation
U.S. Coast Guard
2100 Second St. SW.
Washington, DC 20593-0001
Phone: 202 267-0106

RIN: 2115–AE88

DOT—USCG

95. +SALVAGE AND FIREFIGHTING EQUIPMENT; VESSEL RESPONSE PLANS (USCG-1998-3417)

Priority:

Other Significant

Legal Authority:

33 USC 1321

CFR Citation:

33 CFR 155

Legal Deadline:

None

Abstract:

Current vessel response plan regulations require that the owners or operators of vessels carrying groups I through V petroleum oil as a primary cargo identify in their response plans a salvage company with expertise and equipment, and a company with firefighting capability that can be deployed to a port nearest to the vessel's operating area within 24 hours of notification (groups I-IV) or a discovery of a discharge (group V). Numerous requests for clarification revealed widespread misunderstanding and confusion regarding the regulatory language, which will make the implementation of this requirement difficult. Based on comments received after the Vessel Response Plan final rule publication (61 FR 1052; January 12, 1996) and during a Coast Guard hosted workshop, the Coast Guard intends to better define the terms ''salvage expertise and equipment'' and ''vessel firefighting capability'' requirements and will reconsider the 24-hour deployment requirement which was scheduled to go into effect on February 18, 1998. Therefore, the Coast Guard suspended the effective dates of the 24-hour deployment requirements as published in the final rule. The Coast Guard will continue with this project to better define the requirements. This rulemaking supports the Coast Guard's strategic goals of maritime safety and protection of the natural resources. This rulemaking is DOT-significant because it concerns a matter of substantial public interest or controversy.

Statement of Need:

This rulemaking is intended to reduce the impact of oil spills from vessels.

Summary of Legal Basis:

The statutory authority for this rulemaking is 33 U.S.C. 1321.

Alternatives:

The Coast Guard hosted a workshop to solicit comments from the public on potential alternatives to the marine salvage and firefighting requirements contained in the vessel response plan rule.

Anticipated Cost and Benefits:

Undetermined

Risks:

The purpose of this rulemaking is to better define the terms ''salvage expertise and equipment'' and ''vessel firefighting capability'' requirements and to reconsider the 24-hour deployment requirement. The objective is to improve response and reduce environmental damage from oil spills.

Timetable:

Action	Date	FR Cite
Final Rule - Partial Suspension	02/18/98	63 FR 7069
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

Partial suspension of regulations created through the Vessel Response Plan final rule, docket no. 91-034, RIN 2115-AD81

Agency Contact:

LT Douglas Lincoln
Project Manager
Department of Transportation
U.S. Coast Guard
2100 Second Street SW,
Washington, DC 20593-0001
Phone: 202 267-0448

RIN: 2115–AF60

DOT—Federal Aviation Administration (FAA)

PROPOSED RULE STAGE

96. +FLIGHT OPERATIONAL QUALITY ASSURANCE PROGRAM

Priority:

Other Significant

Legal Authority:

49 USC 44101; 49 USC 44701 to 44702; 49 USC 44705; 49 USC 44709 to 44711; 49 USC 44712; 49 USC 44713; 49 USC 44715; 49 USC 44716 to 44717; 49 USC 44722; 49 USC 44901; 49 USC 44903 to 44904; 49 USC 44912; 49 USC 106(g); 49 USC 40113; 49 USC 40119

CFR Citation:

14 CFR 121; 14 CFR 125; 14 CFR 135

Legal Deadline:

None

Abstract:

The FAA proposes to codify an FAA policy encouraging the voluntary implementation of Flight Operational Quality Assurance (FOQA) programs for the routine analysis of flight data generated during line operations that reveal situations which require corrective action to prevent safety problems. The rule would also clarify the circumstances under which information obtained from voluntary FOQA programs could be used in enforcement actions against air carriers, commercial operators, or airmen. The rule would require air carriers participating in FOQA program to submit aggregate FOQA data to the FAA for use in monitoring safety trends. Under the proposed rule, the FAA may use aggregate FOQA data as a basis to promulgate safety rulemakings or to address situations calling for remedial enforcement action, e.g., a lack of qualification on the part of an operator or aircraft. This rulemaking is significant because of substantial public interest.

Statement of Need:

The primary purpose of a FOQA program is the enhancement of safety. It involves the routine analysis of line operational data to reveal situations that require corrective action and to enable early action before problems occur. Data is collected and aggregated from numerous operations, which is of more value than the assessment of a single situation or event. A secondary benefit of FOQA is a cost savings to the carriers. The collection of aggregated data may point to certain inefficiencies in operations, such as fuel management.

Summary of Legal Basis:

The FAA has broad authority and responsibility to regulate the operation of aircraft and the use of the airspace and to establish safety standards for and regulate the certification of airmen, aircraft, and air carriers. Additionally, on April 5, 2000, the President signed the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century. Section 510 of the Act requires the Administrator to issue a notice of proposed rulemaking proposing ''Flight Operations Quality Assurance Rules''. The proposed rules in this NPRM respond to section 510 and provide safeguards that will ensure that aviation safety is not compromised.

Alternatives:

One alternative is not to propose such a program. This, however, would mean

that the FAA would not be able to collect valuable data that could lead to correction or prevention of safety problems. Another alternative is to obtain the data by other than voluntary means, e.g., monitoring of flight data recorders. This alternative is less desirable since it could lead to an atmosphere of mistrust between the carriers and the FAA. One benefit of FOQA is a communicative and share interest in safety.

Anticipated Cost and Benefits:

The FAA has determined that the costs associated with this rulemaking would be minimal.

Risks:

The costs associated with this rulemaking would be minimal.

Timetable:

Action	Date	FR Cite
Policy Statement	12/07/98	63 FR 67505
NPRM	07/05/00	65 FR 41528
NPRM Comment Period End	10/03/00	
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

Project Number: AFS-93-154R

Agency Contact:

Dan Meier
Flight Standards Service, Regulations Branch
Department of Transportation
Federal Aviation Administration
800 Independence Avenue SW.
Washington, DC 20591
Phone: 202 267-3789

RIN: 2120–AF04

DOT—FAA

97. +OVERFLIGHTS OF UNITS OF THE NATIONAL PARK SYSTEM

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40103; 49 USC 40113; 49 USC 40120; 49 USC 44101; 49 USC 44701; 49 USC 44702; 49 USC 44705; 49 USC 44709; 49 USC 44711 to 44713; 49 USC 44715; 49 USC 44716; 49 USC 44717; 49 USC 44722; 49 USC 46306

CFR Citation:

14 CFR 91; 14 CFR 93; 14 CFR 121; 15 CFR 135

Legal Deadline:

None

Abstract:

The FAA and National Park Service (NPS) established a joint working group which is tasked with developing a notice of proposed rulemaking to reduce or prevent adverse effects of aircraft noise over our national park system. At the same time, the working group is charged with affording those persons who wish to visit our national parks from the air the opportunity to do so. The working group met from May to November 1997, and developed a concept paper that was approved by the Aviation Rulemaking Advisory Committee and the NPS Advisory Board in December 1997. A notice of proposed rulemaking has been developed and is now being reviewed by the FAA and NPS. In April 1999, the FAA issued a disposition of comments to the ANPRM. That document summarizes those comments to the ANPRM and provides an update to the public on matters concerning air tours over units of the national park system. In response to Public Law 106-181, April 5, 2000, the FAA and NPRS are developing an NPRM proposing to codify the language of the legislation and to adopt an altitude that would define a commercial air tour. This rulemaking is significant because of substantial public interest.

Statement of Need:

The need to reduce or prevent the adverse effects of aircraft noise over the national parks is apparent for the preservation of a valuable national resource. In its Report to Congress, the National Park Service identified 98 parks that potentially have an overflight problem. The FAA recognizes its role both to provide for the safe and efficient use of airspace and to enhance the environment by minimizing the adverse effects of aviation in the national parks.

Summary of Legal Basis:

The FAA has broad authority and responsibility to regulate the operation of aircraft and the use of the airspace and to establish safety standards for and regulate the certification of airmen, aircraft, and air carriers. (49 U.S.C. 40101 et seq.) The FAA also has responsibility to protect persons and property on the ground. The President's Memorandum of April 22, 1996, directed the FAA, working with the National Park Service, to issue a notice of proposed rulemaking for the management of sightseeing aircraft in those National Parks where it is deemed necessary to reduce or prevent the adverse effects of noise from such aircraft. Finally, title VIII of Public Law 106-181, National Parks Air Tour Management Act of 2000 gives the FAA the authority to minimize, mitigate or prevent the adverse effect of aircraft over national parks.

Alternatives:

During its working sessions, the working group considered a variety of criteria for defining an air tour, various triggering events for determining which parks are at risk, and various means for the NPS and FAA to work together to develop an air tour management plan.

Anticipated Cost and Benefits:

Undetermined.

Risks:

This rulemaking addresses the risk of destruction of valuable national resources and the right to enjoy the natural quiet in our national parks. At the same time, taking this risk has to be balanced against any potential safety problems that restrictions on overflights might create. Both the National Park Service and FAA are confident that a solution can be reached whereby all visitors to the park may be accommodated through an agreed upon park airspace management plan.

Timetable:

Action	Date	FR Cite
ANPRM	03/17/94	59 FR 12740
ANPRM Correction	04/01/94	59 FR 15350
ANPRM Comment Period End	06/15/94	
Comment Period End 07/15/94	06/20/94	59 FR 31883
Notice of Public Meeting	06/06/97	62 FR 31187
Notice of Public Meeting	04/07/98	63 FR 17040
Disposition of Comments	04/09/99	64 FR 17293
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

Refer to 1999 Regulatory Plan entry RIN 2120-AF93, Airspace Management: Special Flight Rules in the Vicinity of the Grand Canyon and also RIN 2120-AG11, Special Flight Rules in the Vicinity of the Rocky Mountain National Park. Project Number: ARM-97-318A

ANALYSIS: Regulatory Evaluation, 12/00/2000

Agency Contact:

Howard Nesbitt
Flight Standards Service
Department of Transportation
Federal Aviation Administration
800 Independence Avenue SW
Washington, DC 20591
Phone: 202 493-4981

RIN: 2120–AF46

DOT—FAA

98. +FLIGHT CREWMEMBER DUTY PERIOD LIMITATIONS, FLIGHT TIME LIMITATIONS, AND REST REQUIREMENTS

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 40119; 49 USC 44101; 49 USC 44701 to 44701; 49 USC 44705; 49 USC 44709 to 44711; 49 USC 44712; 49 USC 44713; 49 USC 44715; 49 USC 44716 to 44717; 49 USC 44722; 49 USC 44901; 49 USC 44903 to 44904; 49 USC 44912

CFR Citation:

14 CFR 121; 14 CFR 135

Legal Deadline:

None

Abstract:

This rulemaking would amend the regulations on duty period limitations, flight time limitations, and rest requirements for flight crewmembers engaged in air transportation. The FAA proposes additional changes in response to comments received on the NPRM. The changes are necessary to ensure that the rules will continue to provide the minimum level of safety. This rulemaking responds to public and congressional interest in regulating flight crewmember rest requirements, NTSB Safety Recommendations, petitions for rulemaking, and scientific data. This action is considered significant because of substantial public interest.

Statement of Need:

The aviation community requires 24-hour activities to meet operational demands. Growths in long-haul, regional, overnight cargo, and short-haul domestic operations are increasing. Therefore, shift work, night work, irregular work schedules, and time zone changes will continue to be commonplace.

With this growth, the scientific knowledge about sleep, sleep disorders, circadian physiology, fatigue, and performance decrements has also grown. Some of the scientific knowledge has indicated that aviators experience performance-impairing fatigue from sleep loss resulting from current flight and duty practices.

In addition, industry and individuals have told the FAA that the current regulations are confusing and difficult to enforce. Therefore, a second purpose of the rulemaking is to establish consistent and clear duty period limitations and rest requirements for all types of operations.

Summary of Legal Basis:

Section 44701, Title 49 of the United States Code states that the Administrator shall promote safety of flight of civil aircraft in air commerce by prescribing minimum standards required in the interest of safety.

Alternatives:

One obvious alternative would be to continue with the current rules, however, these regulations are rapidly becoming obsolete. As a second alternative, one commenter asked that the FAA develop a standard and then allow each carrier to design a rest/duty program that would meet that standard while accommodating differences in operations. While this works for certain rules, such as training regulations where the standard is training to proficiency, there is no way to apply this application to individual pilots on a daily basis.

Anticipated Cost and Benefits:

Undetermined.

Risks:

Although there has been only one identifiable accident due to pilot fatigue, fatigue is increasingly becoming the focus of possible causes following all accidents. Pilot reports of being fatigued to the point of incapacity are not uncommon, and intuitively, it is reasonable, given the sheer volume of air traffic, to expect fatigue to be a factor in future accidents if the regulations are not corrected.

Timetable:

Action	Date	FR Cite
NPRM	12/20/95	60 FR 65951
NPRM Comment Period End	03/19/96	
Comment Period End 6/19/96	03/20/96	61 FR 11492
SNPRM	03/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Additional Information:

Project Number: AFS-94-443R

ANALYSIS: Regulatory Evaluation, 12/20/95, 60 FR 65951

Agency Contact:

Alberta Brown
Air Transportation Division
Department of Transportation
Federal Aviation Administration
800 Independence Avenue SW
Washington, DC 20591
Phone: 202 267-8321

Quentin Smith
Department of Transportation
Federal Aviation Administration
800 Independence Avenue SW.
Washington, DC 20591
Phone: 202 267-8166

RIN: 2120–AF63

DOT—FAA

FINAL RULE STAGE

99. +CERTIFICATION OF AIRPORTS

Priority:

Other Significant

Legal Authority:

49 USC 106(g); 49 USC 40113; 49 USC 40119; 49 USC 44101; 49 USC 44701 to 44706; 49 USC 44709 to 40711; 49 USC 44713; 49 USC 44716 to 44717; 49 USC 44719; 49 USC 44722; 49 USC 44901; 49 USC 44903 to 44904; 49 USC 44912; 49 46105

CFR Citation:

14 CFR 121; 14 CFR 139

Legal Deadline:

None

Abstract:

This action proposes to revise the current airport certification regulation and to establish certification requirements for airports serving scheduled air carrier operations in aircraft with 10-30 seats. In addition, changes are proposed to address National Transportation Safety Board recommendations and petitions for exemptions and rulemaking. A section of an air carrier operation regulation also would be amended to conform with proposed changes to airport certification requirements. The FAA believes that these proposed revisions are necessary to ensure safety in air transportation and to provide a comparable level of safety at all certificated airports. This action is significant because of substantial public interest.

Statement of Need:

The last major revision to the airport certification regulation occurred in 1987, and since then, industry practices, and technology have changed. To respond to such changes, the FAA is proposing to revise the regulation to clarify and update several requirements. Additionally, with the passage of the 1996 FAA Reauthorization Act, Congress provided the FAA the necessary authority to certificate airports serving scheduled air carrier operations with 10 to 30 seat aircraft, except in the State of Alaska (in addition to existing authority to regulate airports serving air carrier operations using aircraft with more than 30 seats). To achieve a comparable level of safety at all covered airports, FAA now proposes to exercise this authority and amend the regulation to incorporate airports serving smaller air carrier aircraft into the FAA's airport certification program. Also, the 2000 FAA Reauthorization Act (P.L. 106-181) mandates publication of the NPRM within 60 days of the Act's enactment; and publication of the final rule within one year of the close of comment period for airports serving smaller air carrier aircraft.

Summary of Legal Basis:

FAA has general and specific authority to regulate airports as set out in 49 USC 106(g) and 44701.

Alternatives:

The FAA has considered several alternative approaches to this proposed rulemaking and has attempted to minimize the potential economic impact of the proposal; especially the impact on small entities. In addition, this action fulfills the FAA's responsiblilty to meet deadlines established by Congress to certificate airports serving scheduled air carrier operations with 10-30 seat aircraft, except for the State of Alaska. The FAA considered alternatives based on two issues. Issue 1 was the revision of 14 CFR 139, and Issue 2 was the certification of airports serving scheduled operations of small air carrier aircraft with 10-30 passenger seats. The FAA determined that it was necessary to revise 14 CFR 139 and that the revised part 139 should include the certification of airports serving scheduled air carrier operations with 10-30 passenger seat aircraft.

Anticipated Cost and Benefits:

Most of the costs of this proposed rule are associated with the proposed improvements to safety and operational requirements. Most of these costs result from the expansion of ARFF services. The present value of the total cost of the rule over a 10-year period is approximately $46 million, which includes training, additional emergency response protection, wildlife management, and an updated airport certification manual that better reflects current best practices. With the tremendous cost of aviation accidents, the proposed rule provides the potential for enhanced safety for a reasonable cost. The expected benefit of this proposed rule is an enhanced level of safety resulting in reduced fatalities, injuries, and property damage at airports with scheduled air carrier operations, particularly operations in aircraft configured with 10 to 30 passenger seats. The cost of a single accident of a 30-seat scheduled passenger aircraft is greater than the total cost of the proposa. Other benefits of this proposal include provisions for snow and ice control, wildlife management, and training.

Risks:

The purpose of this rulemaking is to expand and enhance the safety benefits of the current regulation by providing, to the extent possible, a comparable level of safety at all airports used by air carriers.

Timetable:

Action	Date	FR Cite
NPRM	06/21/00	65 FR 38636
NPRM Comment Period End	09/19/00	
Final Action	09/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

Project Number: AAS-97-072R.

ANALYSIS: Regulatory Evaluation, 06/21/00

Agency Contact:

Linda Bruce
Office of Civil Aviation Security
Department of Transportation
Federal Aviation Administration
800 Independence Avenue SW
Washington, DC 20591
Phone: 202 267-8553

RIN: 2120–AG96

DOT—Federal Highway Administration (FHWA)

FINAL RULE STAGE

100. +STATEWIDE METROPOLITAN PLANNING

Priority:

Other Significant

Legal Authority:

23 USC 104(f); 23 USC 134; 23 USC 135; 23 USC 217; 23 USC 315; 42 USC 7410 et seq; 49 USC 5305 to 5309

CFR Citation:

23 CFR 450; 49 CFR 613; 49 CFR 1.48(b); 49 CFR 1.51

Legal Deadline:

None

Abstract:

In this action, the FHWA and the FTA are jointly proposing to revise the regulations governing the development of transportation plans and programs for urbanized (metropolitan) areas and States. These revisions are the product of statutory changes made by the Transportation Equity Act for the 21st

Century (TEA-21), which requires a continuous, comprehensive and coordinated process in metropolitan areas and States. The regulation at 23 CFR part 450 is being modified to reflect the impacts of the TEA-21. These changes are being proposed in concert with revisions to regulations concerning environmental impact and related procedures and ITS architecture consistency.

The intent of these changes is to more effectively link planning regulations and environmental streamlining regulations to facilitate integration of decisions, reduce paperwork and analytical activity, where feasible, and to refine procedures and processes to achieve greater efficiency in decisionmaking.

In addition, the agencies believe that an integrated approach to planning and project development will contribute to more effective and environmentally sound decisions regarding investment choices.

Statement of Need:

The Transportation Equity Act for the 21st Century (TEA-21) amended 23 U.S.C. 134 and 135, which require a continuing, comprehensive and coordinated transportation planning process in metropolitan areas and States. Revisions have been proposed for existing regulatory language to make it consistent with current statutory requirements.

Summary of Legal Basis:

Sections 1203, 1204, and 1308 of the TEA-21(Public Law 105-178), amended 23 U.S.C. 134 and 135. Similar changes were made by sections 3004, 3005, and 3006 of the TEA-21 to 49 U.S.C. 5303-5306 which address the metropolitan planning process in the context of the FTA's responsibilities.

Revisions to the current regulation at 23 CFR part 450 have been proposed to reflect the impacts of the TEA-21. The agencies have adopted an approach to the proposed revisions that will rely heavily on guidance and good practice. The proposed regulatory language attempts to respond to legislative mandates and changes with minimal amplification where feasible. In some cases, other factors, e.g., recent court cases, presidential directives, etc., have provided a stimulus for change and amplification. In these instances, the agencies have tried to keep the regulatory language to a minimum except where clarification would assist appropriate agencies and groups in complying.

Alternatives:

Recent court decisions and statutory changes direct at least some modification of existing regulations (e.g., reduction in planning factors from 16 to 7). If regulatory changes are restricted to only those required to reconcile existing law and regulations, the remaining changes could be accomplished through guidance.

Anticipated Cost and Benefits:

The agencies sought comments regarding the potential economic impacts of these proposed rules on small entities and governments. Of specific concern are the additional costs of the incremental changes in regulatory requirements. The agencies believe that these costs have been off-set largely by reduced statutory requirements and the flexibility built into the regulations. The agencies have requested comments on these issues.

Risks:

A failure to issue a regulation could generate increased implementation challenges in working with affected agencies, i.e., difficulty in achieving compliance with expected regulatory outcomes.

Timetable:

Action	Date	FR Cite
NPRM	05/25/00	65 FR 33958
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

State

Agency Contact:

Sheldon M. Edner
Team Leader
Department of Transportation
Federal Highway Administration
Room 3232
400 Seventh Street SW
Washington, DC 20590
Phone: 202 366-4066
Email: sheldon.edner@fhwa.dot.gov

RIN: 2125–AE62

DOT—FHWA

101. +NEPA AND RELATED PROCEDURES FOR TRANSPORTATION DECISIONMAKING; PROTECTION OF PUBLIC PARKS, WILDLIFE AND WATERFOWL REFUGES AND HISTORIC SITES

Priority:

Other Significant

Legal Authority:

42 USC 4321 et seq.; 49 USC 303; 23 USC 109; 23 USC 128; 23 USC 134; 23 USC 138; 23 USC 315; ...

CFR Citation:

23 CFR 530; 23 CFR 540

Legal Deadline:

None

Abstract:

The Federal Highway Administration and the Federal Transit Administration are issuing an NPRM to propose updating and revising the National Environmental Policy Act implementing regulation for FHWA and FTA funded or approved projects. The current regulations were issued in 1987 (23 CFR part 771, August 28, 1987) and experience since that time, as well as changes in legislation, most recently by the Transportation Equity Act for the 21st Century (TEA-21), call for an updated approach to implementation of NEPA for FHWA and FTA projects and actions.

Under this proposed rulemaking, the FHWA/FTA regulation for implementing NEPA would be moved to a new part (23 CFR part 1420) and would be revised to further emphasize using the NEPA process to facilitate effective and timely decisionmaking. Regulatory provisions relating to protection of parkland, wildlife and waterfowl refuges and historic sites would become a separate part (23 CFR 1430).

Statement of Need:

The current NEPA regulation was issued in 1987 and experience since that time, as well as changes in legislation, most recently by the Transportation Equity Act for the 21st Century (TEA-21), call for an updated approach to implementation of NEPA for FHWA and FTA projects and actions.

Summary of Legal Basis:

By including the environmental streamlining provision in section 1309

of the TEA-21, (Public Law 105-178, 112 Stat. 108 at 232), the Congress intended that transportation planning and environmental considerations be better coordinated and that project delivery schedules be improved through a process that is efficient, comprehensive, and streamlined.

Alternatives:

The existing regulation has not been revised since 1987 and has been overtaken by at least two transportation reauthorization bills. It needs to be comprehensively updated to ensure consistency with current statutes and legal precedent. A minimal nonregulatory approach might achieve some desired outcomes, but would be insufficient. Environmental streamlining outcomes will be achieved largely through interagency coordination among Federal resource and permit agencies, but would be more effective if supported by this revision.

Anticipated Cost and Benefits:

It is anticipated that the economic impact of this rulemaking will be minimal. Most costs associated with these rules are attributable to the provisions of the TEA-21, the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), the Clean Air Act (as amended) and other statutes, including earlier highway acts. The agencies consider this proposal to be a means to simplify, clarify, and reorganize existing regulatory requirements.

Risks:

Statutory directives require at least some regulatory changes. Environmental streamlining may be achieved through interagency collaboration, but would be substantially enhanced by the issuance of a final rule.

Timetable:

Action	Date	FR Cite
NPRM	05/25/00	65 FR 33960
Comment Period Extended	07/07/00	65 FR 41892
Comment Period End	09/23/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Additional Information:

This action will incorporate the issues contained in RIN 2125-AD32.

Agency Contact:

Fred Skaer
Office of Environment and Planning
Department of Transportation
Federal Highway Administration
400 Seventh Street SW.
Washington, DC 20590
Phone: 202 366-2058

RIN: 2125–AE64

DOT—National Highway Traffic Safety Administration (NHTSA)

PROPOSED RULE STAGE

102. +FRONTAL OFFSET PROTECTION

Priority:

Other Significant. Major under 5 USC 801.

Legal Authority:

49 USC 322; 49 USC 30111; 49 USC 30115; 49 USC 30117; 49 USC 30166

CFR Citation:

49 CFR 571.208

Legal Deadline:

None

Abstract:

The agency is considering establishing a Federal motor vehicle safety standard for high speed frontal offset crash testing. The frontal offset test is a crash test for automobiles and light trucks in which the subject vehicles are run into a deformable honeycomb barrier. The barrier contacts only 40 percent of the front of the vehicle simulating off-center frontal collision. The agency is considering adding the offset test to the frontal occupant protection standard to measure vehicle structural integrity and reduce the number and severity of lower-body injuries.

Statement of Need:

While the Federal motor vehicle safety standards already contain a frontal crash test, injuries and fatalities still occur in various types of frontal crashes. The European Union determined that the best test for frontal occupant protection would be an offset test with belted test dummies. As part of the House of Representatives Conference Report 104-785, to accompany H.R. 3675, the National Highway Traffic Safety Administration was directed on September 16, 1996, to conduct research ''...toward establishing a Federal motor vehicle safety standard for frontal offset crash testing.'' Such a standard would harmonize with the European Union frontal crash standard. Subsequent research results with the 50th percentile male and the 5th percentile female Hybrid III dummies suggest that additional safety benefits would be provided for the neck and the upper and lower tibia under the offset test conditions.

Summary of Legal Basis:

Section 30111,Title 49 of the United States Code, states the Secretary shall prescribe motor vehicle safety standards. As part of the House of Representatives Conference Report 104-785, to accompany H.R. 3675, the National Highway Traffic Safety Administration was directed on September 16, 1996, to conduct research ''...toward establishing a Federal motor vehicle safety standard for frontal offset crash testing.''

Alternatives:

Since this program is oriented primarily toward adopting an existing European standard, the agency will focus on existing test procedures. However, the agency is working through the national and international biomechanical engineering community to develop better test devices such as improved dummy legs. Comments will be sought on the best dummy designs in the agency's proposal.

Anticipated Cost and Benefits:

A report prepared for the Australian Government estimates that adding an offset test may result in a 15 percent reduction in ''Harm.'' Harm is a calculation of the cost of trauma and is the product of the frequency of injury and cost to the community. Most of these benefits would be seen in reduction in lower body and leg injuries. The agency has not determined the specific benefits of this test procedure.

The agency estimates that for vehicles that cannot currently pass this test, vehicle modifications would cost $14 per vehicle. Based on an estimate that 25 percent of the fleet would need to be modified, the total annual cost to the consumers would be $60 million dollars.

Risks:

Current motor vehicles provide numerous occupant protection systems, such as safety belts and strategically-placed energy absorption materials such as foam padding. However, an estimated 3,300 people per year are

killed and 400,000 people per year are injured in frontal offset crashes.

The agency knows of no disadvantages to implementing this requirement.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Clarke Harper
Division Chief, Light Duty Vehicle Division
Department of Transportation
National Highway Traffic Safety Administration
400 Seventh Street SW.
Washington, DC 20590
Phone: 202 366-2264
Fax: 202 366-4329
Email: charper@nhtsa.dot.gov

RIN: 2127–AH73

DOT—Federal Railroad Administration (FRA)

PROPOSED RULE STAGE

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103. +POSITIVE TRAIN CONTROL

Priority:

Other Significant

Legal Authority:

49 USC 20103

CFR Citation:

49 CFR 234; 49 CFR 236

Legal Deadline:

None

Abstract:

Consistent with Congressional mandate, FRA has continued its commitment to identifying high risk corridors which may better support PTC investment; supporting PTC technology development, testing and compatibility; and promoting deployment of PTC technology on high risk corridors in the near future. In September, 1997, FRA initiated joint fact finding efforts through the Railroad Safety Advisory Committee (RSAC) Working Group on PTC. The advice and recommendations of RSAC will form the basis for proceeding to an NPRM. The rulemaking will address technical standards for PTC, amending 49 CFR part 236.

Statement of Need:

Current FRA regulations do not adequately address the use of signal and train control technology which is processor-based. In fact, application of current regulations to processor-based systems can create absurdly burdensome requirements. Recently, use of this technology has begun to increase on the general system of North American railroads, placing new demands on agency resources to ensure the safety objectives contemplated by the current regulations are achieved. The existence of federal regulations addressing this subject matter would further encourage safe use of the technology, which would reduce the risk of train-to-train collisions, better enforce speed restrictions, and increase the level of protection to roadway workers and their equipment. These improvements will likely result in fewer fatalities, injuries, and economic damage associated with such risks. Given the potential for substantial safety benefits across the spectrum that this program represents, this initiative is extremely important to the agency.

Summary of Legal Basis:

FRA is issuing this proposal pursuant to its general rulemaking authority. 49 U.S.C. 20103(a). Currently, railroads may discontinue or materially alter a signal system initially required by the Secretary of Transportation only with approval from the Secretary. 49 U.S.C. 20502. Exercise of both of these powers has been delegated to the FRA Administrator. 49 C.F.R. 1.49.

Alternatives:

Currently, FRA accepts waiver applications from railroads that seek relief from FRA safety regulations in order to test new signal and train control equipment. Since FRA must consider the safety ramifications of each application on a case-by-case basis, this procedure can take years.

Prior to this action, FRA has considered:(1) leaving the existing regulatory requirements as is, (2) eliminating all regulation of signal and train control systems, and (3) adopting a specification standard for the design of processor-based signal and train control systems. However, agency inaction would hinder introduction of new, safer technology into railroad signal and train control, elimination of all railroad signal and train control system regulation would be a total abdication of the agency's statutory duties, and a specification standard would inhibit innovative signal and train control system designs.

Anticipated Cost and Benefits:

The proposed rule would provide standards for the design of processor-based signal and train control systems, but would not mandate their usage. FRA believes that a railroad would adopt such a system under one or more of the following conditions: (1) the new system is safer; (2) the new system is less expensive; and (3) continued maintenance of the existing system is no longer feasible. The proposed rule would ensure that any replacement system is at least as safe as the current system. Concerning existing processor-based systems, the proposed rule would require railroads to adopt a software management plan, which will ensure proper software configuration, resulting in decreased risk of train accidents due to signal malfunction. FRA has not quantified these benefits because of the difficulties in estimating how many systems are likely to be affected by this rule, what the incremental cost would be, and when the benefits would occur.

Most of the costs of this proposed rule are associated with Safety documentation required to demonstrate compliance with the performance standard. As with many performance standards, this rule would require substantial safety documentation from the railroad to demonstrate compliance, both up front and during the life cycle of the system. It appears that the primary cost involved in this proposed rule will be the product risk assessment, a one-time expense presently incurred by product suppliers. For current processor-based systems, railroads face the cost of implementing a software management control plan, which is less expensive than attempting to satisfy current requirements, which did not contemplate the use of processor-based technology.

Overall, it appears that the benefits of the proposed rule outweigh the costs.

Risks:

The risk category addressed by the proposed rule is that of accidents which occur due to improper signaling or train control. This may result in train-to-train collisions, derailments due to excessive train speed, and trains

penetrating the work limits of roadway workers.

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Additional Information:

FRA has separated out of this rulemaking its action entitled Radio Communication, which revised its radio rules for more flexibility and to include requirements for the presence of radios and/or some means of wireless communication (RIN 2130-AB19).

Agency Contact:

David T. Matsuda
Trial Attorney
Department of Transportation
Federal Railroad Administration
400 Seventh Street SW.
Washington, DC 20590
Phone: 202 493-6046

RIN: 2130–AA94

DOT—FRA

FINAL RULE STAGE

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104. +WHISTLE BANS AT HIGHWAY-RAIL GRADE CROSSINGS

Priority:

Other Significant

Legal Authority:

49 USC 20153

CFR Citation:

49 CFR 222

Legal Deadline:

Final, Statutory, November 2, 1996.

Abstract:

This action would govern when and how train whistles at grade crossings must be sounded. FRA has found that failing to use the locomotive horn can significantly increase the number of collisions with motorists using the crossing. This action is considered significant because of substantial public interest. This action is being taken pursuant to statutory mandate. FRA studied the consequences of the proposed action and prepared a draft environmental impact statement (EIS) for the proposed rule.

Statement of Need:

This rule is required by the Swift Development Act of 1994 (Act). The Act requires the use of locomotive horns at every public highway-rail grade crossing but gives FRA the authority to make reasonable exceptions. Congress amended this law in 1996 to require that FRA take into account the interest of the communities with pre-existing restrictions on locomotive horns.

Summary of Legal Basis:

Issuance of this rule is required by 49 USC 20153.

Alternatives:

There was no alternative to initiating this rulemaking, as it is required by statute. However, the rule would provide a list of supplementary measures the FRA has determined to be effective substitutes for the locomotive horn in the prevention of highway-rail grade crossing casualties. The rule would also allow for whistle bans if there are alternative safety measures that compensate for the lack of a locomotive horn.

Anticipated Cost and Benefits:

The problems considered by this rule are collisions and their associated casualties and property damage involving vehicles on public highways and the front ends of trains at whistle-ban grade crossings.

The costs of this rulemaking will be incurred predominantly by communities. However, there are also costs to railroads and to the Federal government. At this time, FRA does not know how many businesses would be impacted or the severity of the impact if a community elects to follow the mandate and become subject to whistleblowing at crossings. Nevertheless, the estimated benefits in terms of lives saved and injuries prevented will exceed the costs imposed on society for the proposed rule. Even under the best case scenario (falling collision rates over time) the safety benefits alone, excluding any benefit to railroads, exceed the most costly realistic scenario for community safety enhancements.

Risks:

As a result of studies conducted on accident rates at crossings at which locomotive horns are banned, FRA has concluded that such crossings generally result in a higher risk of accident than at crossings at which horns are sounded. FRA has compared the number of collisions occurring within ten different groups of crossings grouped by risk and found that the risk of a collision was 62 percent greater at crossings equipped with automatic gates and flashing lights than at similarly equipped crossings across the nation without bans. FRA analysis also indicated that whistle ban crossings without gates, but equipped with flashing light signals and/or other types of active warning devices, on average, experienced 119 percent more collisions than similarly equipped crossings without whistle bans. Congress requires that FRA issue a regulation requiring the sounding of locomotive horns at all public highway rail grade crossings. However, an exception to the requirement is permissible in circumstances in which there is not a significant risk of loss of life or serious personal injury, use of the locomotive horn is impractical, or supplementary safety measures fully compensate for the absence of the warning provided by the horn. Issuance of the rule would lower the increased collision risk associated with crossings at which no locomotive horns are sounded.

Timetable:

Action	Date	FR Cite
NPRM	01/13/00	65 FR 2230
NPRM Comment Period End	05/26/00	
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

State, Local

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

Mark Tessler
Trial Attorney
Department of Transportation
Federal Railroad Administration
400 Seventh Street SW.
Washington, DC 20590
Phone: 202 493-6061

RIN: 2130–AA71

DOT—Research and Special Programs Administration (RSPA)

PROPOSED RULE STAGE

105. +APPLICABILITY OF THE HAZARDOUS MATERIALS REGULATIONS TO LOADING, UNLOADING, AND STORAGE

Priority:

Other Significant

Legal Authority:

49 USC 5101 to 5127

CFR Citation:

49 CFR 106 to 107; 49 CFR 171 to 180

Legal Deadline:

None

Abstract:

This rulemaking proposes to better define the applicability of the Federal Hazardous Materials Regulations (HMR) in order to clarify the relationship among Federal, State, local, and tribal agencies in the regulation of hazardous materials. Under circumstances specified in Federal statutes, the regulations of other Federal agencies (EPA and OSHA) and non-Federal governments (States, localities, and Indian tribes) must be consistent with or defer to RSPA's regulation of the transportation of hazardous materials in commerce. However, other Federal and non-Federal requirements are generally not limited where hazardous materials are not in transportation. Activities relating to loading, unloading, and storage of hazardous materials have become areas of particular uncertainty and concern to both industry and non-Federal governments. This action is significant because of the substantial public interest in reducing uncertainty and avoiding conflicting regulations.

Statement of Need:

In recent years, RSPA has issued interpretations and administrative decisions on a case-by-case basis about whether particular activities are in ''transportation'' and therefore subject to regulation under the HMR. Because of increasing State and local regulation of hazardous materials, RSPA concluded that an overall rulemaking is appropriate, rather than just case-by-case decisions. RSPA believes that better overall definitions of the applicability of the HMR will reduce uncertainty by the regulated community and other regulatory agencies (both Federal and non-Federal) as to which agency has regulatory authority. Greater certainty in this regard should promote improved compliance with the HMR and also with the requirements of other regulatory agencies.

Summary of Legal Basis:

Section 5103 of title 49 U.S.C. specifies that the Secretary shall prescribe regulations for the safe transportation of hazardous materials in intrastate, interstate, and foreign commerce applicable to, among others, any person who offers hazardous materials for transportation or who transport hazardous materials in commerce. In addition, section 5125 of title 49 U.S.C. sets forth the circumstances under which differing non-Federal requirements are preempted.

Alternatives:

Commenters to the ANPRM and SANPRM suggested alternative ways to describe the applicability of the HMR. One suggestion is to describe the applicability of the HMR in relationship to specific transportation functions. Another is to describe the applicability of the HMR over specific regulated entities, such as those who offer hazardous materials for transportation or those who transport hazardous materials. RSPA is considering each of the alternatives proposed.

Anticipated Cost and Benefits:

The potential costs and benefits of this action have not been determined. A preliminary regulatory evaluation will be developed.

Risks:

Clarifying the applicability of the HMR should reduce uncertainty as to which regulatory agency's requirements apply to any particular activity involving hazardous materials and improve compliance with the HMR, the requirements of EPA and OSHA, and non-Federal requirements. This should result in improved compliance with the applicable regulatory requirements, and improve hazardous materials transportation safety, reduce risks to the environment from hazardous materials, and promote workplace safety at facilities that manufacture or handle hazardous materials.

Timetable:

Action	Date	FR Cite
ANPRM	07/29/96	61 FR 39522
ANPRM Comment Period End	11/30/96	
SANPRM	04/27/99	64 FR 22718
Extension Comment Period Published for SANPRM	07/26/99	
SANPRM Comment Period End	08/25/99	
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

Docket No. HM-223. As a result of comments received to the ANPRM, we have upgraded this rulemaking to significant.

Agency Contact:

Susan Gorsky
Senior Regulations Specialist
Department of Transportation
Research and Special Programs Administration
400 Seventh Street SW.
Washington, DC 20590
Phone: 202 366-8553
Email: rules@rspa.dot.gov

RIN: 2137–AC68

BILLING CODE 4910–62–S

DEPARTMENT OF THE TREASURY (TREAS)

Statement of Regulatory Priorities

The primary missions of the Department of the Treasury are: promoting domestic economic growth and maintaining our Nation's leadership in global economic issues; protecting and collecting the revenue under the Internal Revenue Code and customs laws; financing the Federal government and managing its fiscal operations; supervising national banks and thrift institutions; enforcing laws relating to counterfeiting, Federal government securities, firearms and explosives, money laundering, foreign commerce in goods and financial instruments, and smuggling and trafficking in contraband; administering the Community Development Financial Institutions Fund and its programs; protecting the President, Vice President, certain foreign diplomatic personnel, and others; training Federal, State, and local law enforcement officers; and producing coins and currency.

Consistent with these missions, most regulations of the Department and its constituent bureaus are promulgated to interpret and implement the laws as enacted by the Congress and signed by the President. Unless circumstances require otherwise, it is the policy of the Department to issue a notice of proposed rulemaking (NPRM) and carefully consider public comments before adopting final regulations. Also, in particular cases, the Department invites interested parties to submit views on rulemaking projects while the NPRM is being developed, and holds public hearings to discuss proposed rules.

To the extent permitted by law, it is the policy of the Department to adhere to the regulatory philosophy and principles set forth in Executive Order 12866, and to develop regulations that maximize aggregate net benefits to society, while minimizing the economic and paperwork burdens imposed on persons and businesses subject to those regulations.

Internal Revenue Service

The Internal Revenue Service (IRS), working with the Office of the Assistant Secretary (Tax Policy), promulgates regulations that interpret and implement the Internal Revenue Code and related tax statutes. The purpose of these regulations is to carry out the tax policy determined by Congress in a fair, impartial and reasonable manner, taking into account the intent of Congress, the realities of relevant transactions, the need for the Government to administer the rules and monitor compliance, and the overall integrity of the Federal tax system. The goal is to make the regulations practical and as clear and simple as possible.

Most IRS regulations interpret tax statutes to resolve ambiguities or fill gaps in the tax statutes. This includes interpreting particular words, applying rules to broad classes of circumstances, and resolving apparent and potential conflicts between various statutory provisions.

During fiscal year 2001, the IRS will accord priority to the following regulatory projects:

- *Hope Scholarship and Lifetime Learning Credits*. The Taxpayer Relief Act of 1997 added section 25A to the Internal Revenue Code. Section 25A authorizes the allowance of Hope Scholarship and Lifetime Learning tax credits with respect to certain qualified tuition and related expenses incurred after 1997. Proposed regulations were issued under section 25A in 1999. The IRS will issue final regulations to provide rules for taxpayers that claim the nonrefundable Hope Scholarship and the Lifetime Learning tax credits against their Federal income taxes for certain post-secondary education expenses. The regulations will, among other things: provide rules regarding eligibility for, and calculation of, the credits; provide definitions for certain statutory terms; describe the adjustments required for certain excludable educational assistance; and set forth the time for claiming an education credit. The IRS will also issue final regulations under section 6050S to provide guidance to educational institutions so they can provide information reporting to students and the IRS with respect to amounts eligible for the Hope Scholarship and Lifetime Learning tax credits.
- *Recognition of Gain on Certain Distributions of Stock or Securities under Section 355(e)*. Congress enacted section 355(e) of the Internal Revenue Code as part of the Taxpayer Relief Act of 1997 and made technical corrections to that section in the Internal Revenue Service Restructuring and Reform Act of 1998. Section 355(e) provides that the distributing corporation will recognize gain on certain distributions that are part of a plan (or series of related transactions) pursuant to which one or more persons acquires directly or indirectly stock representing a 50-percent or greater interest in the distributing or controlled corporation. Regulations will be issued concerning the interpretation of the phrase plan (or series of related transactions).
- *Source of Income Received from Space or Ocean-Based Activities*. The IRS will issue regulations under Internal Revenue Code section 863 addressing the source of income received by U.S. and foreign persons for activities conducted in space, or on or under water outside of the jurisdiction of any country. The regulations will address the source of income received from the transmission of communications or data from the United States to a foreign country, or from a foreign country to the United States. Since the existing rules under section 863 were issued in 1986, there have been many technological developments in the space and communications industry. Regulations are needed to conform the existing source rules to these technological developments.
- *Excise Taxes on Excess Benefit Transactions*. Internal Revenue Code section 4958 imposes excise taxes on non-fair market value transactions between certain tax-exempt organizations and persons in positions to exercise substantial influence over those organizations (disqualified persons). Disqualified persons who benefit economically from the excess benefit transactions (and in certain instances, the organization managers) are liable for the taxes. The IRS expects to issue regulations that will clarify various rules, definitions, and safe harbors under section 4958.
- *Payment by Credit Card and Debit Card*. The Taxpayer Relief Act of 1997 authorized the Secretary to issue regulations under Internal Revenue Code section 6311 to receive payment of internal revenue taxes by commercially acceptable means, including payment by credit cards and debit cards. Temporary regulations were issued in 1998 to implement these new payment mechanisms. In FY 2001, the IRS intends to issue final regulations concerning payment of taxes by credit cards (including charge cards) and debit cards.

Office of the Comptroller of the Currency

The Office of the Comptroller of the Currency (OCC) charters, regulates, and supervises national banks to ensure a

safe, sound, and competitive national banking system that supports the citizens, communities, and economy of the United States. The substantive content of the OCC's regulations reflects four organizing principles that support this mission:

- The OCC's regulations help ensure safety and soundness by establishing standards that set the limits of acceptable conduct for national banks.
- The OCC's regulations promote competitiveness by facilitating a national bank's ability to develop new lines of business, subject to any safeguards that are necessary to ensure that the bank has the expertise to manage risk effectively and adapt its business practices to deal responsibly with its customers.
- Regulations can also affect national banks' ability to compete by contributing significantly to their costs. The OCC's goal is to improve efficiency and reduce burden by updating and streamlining its regulations and eliminating those that no longer contribute significantly to the fulfillment of its mission.
- The OCC's regulations help assure fair access to financial services for all Americans by removing unnecessary impediments to the flow of credit to consumers and small businesses, by encouraging national banks' involvement in community development activities, and by implementing Federal laws designed to protect consumers of financial services.

The OCC's regulatory workload and plans are affected directly by new statutes. Possible statutory changes are not addressed in this **Regulatory Plan**, but may affect some of the planned rules directly, and likely would affect how the OCC prioritizes its regulatory workload.

Important final and interim rules issued during fiscal year 2000 (or expected to be issued before publication of this **Regulatory Plan**) include:

- *National Bank Financial Subsidiaries* (12 CFR part 5). The OCC amended its regulations to implement section 121 of the Gramm-Leach-Bliley Act (GLBA) (Pub. L. 106-102), which authorizes national banks to conduct expanded financial activities through financial subsidiaries. The OCC also revised its operating subsidiary rule to make conforming changes and streamline procedures for banks that engage in activities through operating subsidiaries. Finally, the OCC revised its regulation governing other equity investments to make corresponding changes to the procedures for certain types of non-controlling investments.
- *Financial Privacy* (12 CFR part 40). This rule, issued jointly with the other Federal banking agencies and prepared in consultation with the Department of the Treasury, the Securities and Exchange Commission, the Federal Trade Commission, and the National Credit Union Administration, implemented the notice and opt out provisions in title V of the GLBA.
- *Privacy-Safety and Soundness Standards* (12 CFR part 30). This rulemaking, conducted jointly with the other banking agencies, will establish standards governing the administrative, technical, and physical safeguards of bank and customer records.
- *Fair Credit Reporting Act* (12 CFR part 41). This rule, also to be issued with the other Federal banking agencies, will implement the affiliate sharing provisions of the Fair Credit Reporting Act. In order to minimize the burden of this rule, the agencies expect that it will adopt many of the provisions governing content of disclosures and the method of delivery that were adopted in the financial privacy rule.
- *Risk-Based Capital Treatment of Recourse and Direct Credit Substitutes* (12 CFR part 3). Among other things, this rule would: (1) treat recourse obligations and direct credit substitutes comparably; (2) use credit ratings to assign risk weights to credit enhancements and asset-backed securities; and (3) permit the use of bank internal risk ratings for certain limited purposes.
- *Insurance-Customer Protections* (12 CFR part 14). This rule, published jointly with the other Federal banking agencies pursuant to section 47 of the GLBA, prescribes consumer protection regulations that apply to retail sales practices, solicitations, advertising, or offers of any insurance product by a depository institution or any person that is engaged in such activities at an office of the institution or on behalf of the institution.
- *Insurance-Debt Cancellation Contracts* (12 CFR part 14). The OCC issued an advance notice of proposed rulemaking (ANPRM) inviting comments on whether the OCC should issue regulations that would provide consumer-related protections for debt cancellation contracts (which are contracts between borrowers and creditors that suspend a debt because of events such as death, unemployment, etc.).
- *Community Reinvestment Act-Disclosure* (12 CFR part 25). The OCC, along with the other Federal banking agencies, issued proposed rules that would require procedures to ensure compliance with the sunshine requirements of the Community Reinvestment Act. Pursuant to these requirements, nongovernmental entities or persons, insured depository institutions, and affiliates of insured depository institutions that are parties to certain agreements that are in fulfillment of the Community Reinvestment Act of 1977 must make the agreements available to the public and the appropriate agency and file annual reports concerning the agreements with the appropriate agency.
- *Electronic Banking*. The OCC published an ANPRM inviting interested parties to comment on a wide range of issues involving national bank involvement in electronic banking. The goal of the ANPRM is to determine whether the OCC's regulations should be revised to remove regulatory impediments and unnecessary burdens, if any, to bank use of technology, or add new provisions that would facilitate national banks' use of new technologies.
- *Community Banks*. The OCC has published another ANPRM inviting interested parties to comment on whether there are ways the OCC could reduce burden on community banks in, among other areas, capital, lending limits, corporate governance, and applications processing.

The OCC's regulatory priorities for fiscal year 2001 include projects in the following areas:

- *Risk-Based Capital Standards* (12 CFR part 3). The OCC will continue to work with the other Federal banking agencies to update the risk-based capital standards to maintain, and, where necessary, improve consistency in the agencies' rules. Regulatory projects in this area may include the following:

  Collateralized Transactions. The rule would conform the rules of the other banking agencies to the OCC's rule regarding the risk-based capital treatment of loans collateralized in cash or government securities issued by members of the Organization for Economic Cooperation and Development (OECD). The rule would assign a zero risk weight for the portion of claims collateralized by cash on deposit in a bank or securities issued or guaranteed by the U.S.

Government or its agencies or the central government of an OECD country, provided that certain conditions are met.

Risk-Based Capital Treatment of Recourse Transactions and Direct Credit Substitutes. The OCC intends to finalize the rulemaking summarized above in which the OCC and other Federal banking agencies have sought comment on changes that would result in more consistent treatment of recourse obligations and similar transactions among the agencies, more consistent risk-based capital treatment for certain types of transactions involving similar risk, and capital requirements that more closely reflect a banking organization's relative exposure to credit risk.

Residual Interests. The OCC is considering proposing a dollar-for-dollar capital charge on all subordinated positions, either retained or purchased by a bank, that serve as credit enhancement on a securitization. The dollar-for-dollar capital charge would apply to interests totaling up to 25 percent of Tier 1 capital, after which any remaining interest would be directly deducted from Tier 1 capital.

- *Bank Activities and Operations* (12 CFR part 7). The OCC intends to publish a notice of proposed rulemaking (NPRM) inviting comment on several proposed amendments to part 7, possibly including amendments addressing bank holidays, the ability of a bank to participate in financial education programs with schools without the school being treated as a branch of the bank, and a clarification of the OCC's fee regulation.
- *Fiduciary Activities of National Banks* (12 CFR part 9). The OCC is considering possible amendments to its regulation to address issues confronted by national banks that engage in fiduciary activities on an interstate basis. These amendments might include, for instance, a codification of recent OCC Interpretive Letters that analyzed the effect of State laws that would have the effect of preventing national banks to establish trust offices and trust representative offices.
- *Real Estate Lending and Appraisals* (12 CFR part 34). The OCC intends to evaluate its rules governing adjustable rate mortgage loans to determine whether the rule continues to implement the Alternative Mortgage Transaction Parity Act of 1982 effectively and whether additional safeguards against predatory lending are needed.
- *Electronic Banking.* Pursuant to comments and suggestions made in response to the ANPRM summarized above, the OCC will address ways to facilitate national banks in their efforts to engage in various forms of electronic banking. These might include, by way of illustration, provisions affecting digital certificates, electronic data storage, and the establishment of transactional Web sites.

Office of Thrift Supervision

As the primary Federal regulator of the thrift industry, the Office of Thrift Supervision (OTS) has established regulatory objectives and priorities to supervise thrift institutions effectively and efficiently. These objectives include maintaining and enhancing the safety and soundness of the thrift industry; a flexible, responsive regulatory structure that enables savings associations to provide credit and other financial services to their communities, particularly housing mortgage credit; and a risk-focused, proactive approach to supervision.

OTS is reviewing its lending regulations, including the rules implementing the Alternative Mortgage Parity Act, to determine whether and how they may be improved to encourage responsible lending to underserved markets and address predatory lending practices. OTS also plans to revise its lending regulations to enable thrifts to better serve their communities and compete with national and state banks.

OTS also plans to issue a final rule revising its regulations governing conversion from mutual to stock or mutual holding company form and a proposed rule that would require certain holding companies to notify OTS before they engage in significant new activities.

In addition, OTS intends to publish a number of proposed rules as part of its ongoing effort to review and streamline its regulations. These proposals, which will be drafted in the plain language format, include rules revising the application processing procedures, regulations on types of offices, and rules on directors and officers.

OTS also has a number of regulatory projects underway implementing new legislation in the Gramm-Leach-Bliley Act (GLBA) (Pub. L. 106-102). These projects include:

- *Community Reinvestment Act-Disclosure.* OTS intends to issue joint final rules with the other Federal banking agencies requiring disclosure and reporting of Community Reinvestment Act agreements.
- *Insurance Customer Protections.* The four Federal banking agencies also plan to issue proposed and final rules providing customer protections relating to sales practices, disclosures, and advertising insurance products and annuities by depository institutions, at the offices of depository institutions, and on behalf of depository institutions.
- *Fair Credit Reporting.* OTS and the other Federal banking agencies will issue joint proposed and final rules implementing provisions of the Fair Credit Reporting Act concerning information sharing with affiliates
- *Safeguarding Customer Information.* The Federal banking agencies will also issue joint proposed and final rules setting standards for administrative, technical, and physical safeguards for customer records and information.
- *Holding Companies.* OTS is reviewing its current holding company regulations to determine how they should be modified to reflect statutory changes made by GLBA.

OTS also will continue to work with the other Federal banking agencies to update capital standards to maintain, and, where necessary, improve consistency in the agencies' rules. Regulatory projects in this area may include the following:

- *Risk-Based Capital Treatment of Recourse and Direct Credit Substitutes.* Among other things, OTS plans to issue a final rule jointly with the other Federal banking agencies that would: (1) treat recourse obligations and direct credit substitutes comparably; (2) use credit ratings and certain other alternative mechanisms to match risk-based capital requirements more closely to a depository institution's risk of loss in asset securitizations; and (3) require the sponsor of a revolving credit securitization that involves an early amortization feature to hold capital against the amount of assets under management.
- *Capital Adequacy.* OTS, along with the other Federal banking agencies, plans to issue a joint advance notice of proposed rulemaking seeking comment on ways to simplify the capital adequacy framework for small, noncomplex institutions.
- *Residuals in Securitizations.* OTS and the other Federal banking agencies plan to issue a proposed rule that would better align regulatory capital requirements with the risk exposure of certain residual interests in asset

securitizations and other transfers of assets.
- *Claims on Securities Firms*. The four Federal banking agencies plan to issue a proposed rule that would reduce the risk weight assigned to claims on, and claims guaranteed by, qualifying securities firms.
- *Collateralized Transactions*. This final rule would conform the rules of OTS and the other banking agencies to the OCC's rule regarding the risk-based capital treatment of loans collateralized in cash or OECD government securities. The rule would assign a zero risk weight for the portion of claims collateralized by cash on deposit in a bank or securities issued or guaranteed by the U.S. government or its agencies or the central government of an OECD country, provided that certain conditions are met.
- *Miscellaneous Capital Revisions*. OTS also plans to issue a proposed rule to make miscellaneous amendments to update its capital rules.

United States Customs Service

The United States Customs Service (Customs) is responsible, among other things, for administering laws concerning the importation of goods into the United States. This includes inspecting imports, collecting applicable duties, overseeing the activities of persons and businesses engaged in importing, and enforcing the laws concerning smuggling and trafficking in contraband. The regulatory priorities of Customs for fiscal year 2001 are to continue to facilitate procedures for legitimate commercial transactions and to provide further obstacles to the flow of narcotics and other contraband into the United States.

During fiscal year 2000, one of Customs' priorities was to continue to move forward with amendments reinventing its regulatory procedures that began under the authority granted by the Customs Modernization provisions of the North American Free Trade Implementation Act (Customs Mod Act). Customs' reinvention efforts, in accordance with the principles of Executive Order 12886, have involved and will continue to involve significant input from the importing public. Customs' reinvention efforts also involve testing of programs to see if they work before proceeding with proposed rulemaking to permanently establish the programs. Many final rules implementing the Customs Mod Act were published during the past fiscal year. These rules included:
- *Customs Brokers*. This rule made significant revisions to the regulations concerning the licensing and conduct of customs brokers in the performance of customs business on behalf of others.
- *Drawback*. This rule established new procedures applicable to the filing of false drawback claims that result in the imposition of penalties.
- *Underpayments and Overpayments*. This rule conformed Customs' regulations to statutory provisions and judicial precedent regarding the assessment of interest as a result of underpayments or overpayments duties, taxes and fees pertaining to imported merchandise.
- *Penalties*. This rule established guidelines for the imposition and mitigation of penalties for violations of 19 U.S.C. 1592

Customs also expects to propose in late FY 2000 or early FY 2001 revisions to the procedures by which Customs will issue administrative rulings responding to requests from prospective importers concerning how Customs will treat their transactions. Customs plans to finalize these rules during FY 2001.

During fiscal year 2001, Customs will continue implementing the Customs Mod Act. Customs plans to finalize revisions to its procedures regarding protests. Customs will also be developing and publishing regulations to implement provisions of the Trade and Development Act of 2000. These projects will include amendments to existing regulations concerning the Caribbean Basin Initiative (CBI) and the Generalized System of Preferences, as well as new regulations concerning the African Growth and Development and the CBI enhancement provisions of the Trade and Development Act.

During the fiscal year 2001, Customs also plans to undertake several other regulatory projects that will affect the traveling and importing public, customs brokers, carriers and commercial importers. Customs will accord priority to several projects to foster the development of a more automated environment to expedite the entry, processing, and release of imported commercial merchandise, and the clearance of merchandise for export. These regulations will benefit the importing and exporting public by streamlining the work of Customs officers and the trade community through improved efficiency and reduced paperwork and administrative costs. Among these projects are:
- *Liquidations*. Customs will propose regulations allowing paperless procedures for extension and suspension of liquidation notices, improving and clarifying the administrative process and simplifying the regulations pertaining to liquidations and extensions and suspensions of liquidation.
- *Entry Reconciliation*. Customs will continue to develop through testing a ''reconciliation'' process that will allow the delayed submission to Customs of information that is undetermined at the time an entry summary or an import activity summary statement is required to be submitted. This process will facilitate the movement of imported merchandise. After Customs is satisfied with the testing, regulations will be proposed to allow reconciliation on a permanent basis.
- *Remote Location Filing*. Customs will propose regulations allowing electronic filing of entries from locations in the United States other than the port of arrival of the merchandise or the place at which the merchandise is examined. Remote location filing will provide entry filers (such as brokers and couriers) with greater flexibility and will allow Customs to make more efficient use of its resources.

Bureau of Alcohol, Tobacco and Firearms

The Bureau of Alcohol, Tobacco and Firearms (ATF) issues regulations to enforce the Federal laws relating to the manufacture and commerce of alcohol products, tobacco products, firearms, and explosives. ATF's regulations carry out these missions and are designed to:
- Curb illegal traffic in, and criminal use of, firearms; and to assist State, local, and other Federal law enforcement agencies in reducing crime and violence;
- Facilitate investigations of violations of Federal explosives laws and arson-for-profit schemes;
- Regulate the alcohol, tobacco, firearms, and explosives industries, including the issuance of licenses and permits;
- Assure the collection of all alcohol, tobacco, firearms, and ammunition taxes, and obtain a high level of voluntary compliance with all laws governing those industries;
- Suppress commercial bribery, consumer deception and other prohibited practices in the alcoholic beverage industry; and
- Assist the States in their efforts to eliminate interstate trafficking in, and the sale and distribution of, cigarettes in avoidance of State taxes.

ATF intends to streamline its regulations applying to the brewing industry by simplifying its brewery reports and operations and eliminating obsolete regulatory provisions. Also, ATF will propose minimum production standards for beer, thereby reducing formula filings and a revised statement of net contents requirement for certain container sizes.

ATF will continue, as a priority during Fiscal Year 2001, the multifaceted regulatory project governing various modifications to its regulations governing commerce in explosives. ATF is further analyzing its regulations governing storage requirements for explosives, including fireworks explosive materials, and plans to issue the notice of proposed rulemaking described in detail in part II of this **Regulatory Plan**.

Financial Crimes Enforcement Network

The regulations of the Financial Crimes Enforcement Network (FinCEN) constitute the core of Treasury's anti-money laundering initiatives and are an essential component of Treasury's anti-narcotics effort. The Bank Secrecy Act (BSA) authorizes the Secretary of the Treasury to issue regulations requiring financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax or regulatory proceedings, and to implement counter-money laundering programs and compliance procedures.

Since mid-1994, FinCEN has been engaged in a thorough review of its regulatory policies and has been building a partnership between government and the financial sector to fight money laundering. The cornerstone of that partnership is the recognition that only a cooperative relationship between government and industry can provide a way to implement a three-pronged strategy of prevention, detection, and enforcement against those who seek to use the financial system to promote or further illegal activity. FinCEN recognizes that BSA compliance imposes costs on the financial community and that recordkeeping and reporting should be required only when the benefits to law enforcement efforts are clear.

During fiscal year 2001, FinCEN will continue to review and revise its existing regulations. FinCEN will continue to work with the financial community to reduce administrative burdens associated with complying with the law while enhancing the usefulness of BSA information for law enforcement, financial regulators and policymakers. FinCEN is continuing a general revision and simplification of all of its regulations and will accord priority to the issuance of a final rule based on a 1998 notice of proposed rulemaking requiring the reporting of suspicious transactions by casinos and card clubs. FinCEN will also publish for public comment a proposal to require brokers and dealers in securities to report suspicious transactions.

Bureau of the Public Debt

The Bureau of the Public Debt (BPD) administers regulations governing transactions in government securities by government securities brokers and dealers and regulations that implement Treasury's borrowing authority, including rules governing the sale and issue of marketable Treasury securities. BPD also administers the rules issued in January 2000 that set out the terms and conditions by which Treasury may redeem (buyback) outstanding, unmatured marketable Treasury securities through debt buyback operations. BPD also is responsible for administering the regulatory provisions governing the types and valuations of collateral that are acceptable to secure deposits of public monies and other financial interests of the Federal Government.

The Government Securities Act of 1986 (GSA) authorizes the Secretary of the Treasury to prescribe rules governing financial responsibility, the protection of customer funds and securities, recordkeeping, reporting, audit, and large position reporting for all government securities brokers and dealers, including financial institutions. These rules fulfill the Treasury's statutory responsibility to safeguard the efficient functioning of the government securities market and are designed to prevent fraudulent and manipulative acts and practices and to protect the integrity, efficiency, and liquidity of the market. The Department and BPD are committed to implementing rules that make sense from both a regulatory and market efficiency perspective. Accordingly, the Department and BPD seek to balance the benefits of regulation with the compliance costs imposed on the government securities market and its participants.

The rules setting out the terms and conditions for the sale and issue of marketable book-entry Treasury bills, notes and bonds are known as the uniform offering circular. These rules apply to securities held in accounts in the book-entry system established by the Department and operated by the Federal Reserve Banks, known as the commercial book-entry system, as well as to securities held in accounts directly with Treasury in the *Treasury Direct* system. The uniform offering circular describes the types of securities offered for sale, the auction methods by which they are sold, the process by which bidders submit bids, the process for awarding securities to successful bidders and the authorized payment methods.

During fiscal year 2001, BPD will accord priority to rewriting the uniform offering circular in plain language. This will communicate the auction rules in a more direct and effective manner. Also, BPD will propose technical revisions to its GSA regulations to conform to the amendment to the definition of government securities in the Securities Exchange Act of 1934 that was enacted by section 208 of the Gramm-Leach-Bliley Act.

Financial Management Service

The Financial Management Service (FMS) issues regulations to improve the quality of Government financial management and to administer its payments, collections, debt collection, and Governmentwide accounting programs. During fiscal year 2001, FMS will update its regulations that implement the Cash Management Improvement Act of 1990 (CMIA). The CMIA requires the head of each executive agency, under regulations prescribed by the Secretary of the Treasury, to provide for the timely disbursement of Federal funds through cash, checks, electronic funds transfer, or any other means identified by the Secretary of the Treasury. FMS issued an implementing regulation in December 1992. FMS intends to issue a notice of proposed rulemaking to update the CMIA in early fiscal year 2001 and expects to finalize the rule later in the year.

Also in fiscal year 2001, FMS will revise its rule concerning the payment of Federal taxes and the Treasury Tax and Loan Program. FMS plans to revise its rule to support operational changes to the system used for the collection of corporate withholding taxes, as well as to streamline the rule and convert it to the plain language standard. FMS intends to issue a notice of proposed rulemaking to implement these revisions in late 2000, and expects to publish a final rule by mid 2001.

Finally, FMS will continue to implement provisions of the Debt Collection Improvement Act of 1996.

FMS, in conjunction with the Department of Justice, will finalize the rule containing Federal Claims Collection Standards, which establishes standards for Governmentwide debt collection.

Community Development Financial Institutions Fund

The Community Development Financial Institutions Fund (Fund) was established by the Community Development Banking and Financial Institutions Act of 1994 (12 U.S.C. 4701 *et seq.*). The primary purpose of the Fund is to promote economic revitalization and community development through investments in, and assistance to, community development financial institutions (CDFIs), principally through the CDFI Program.

The Fund administers the Bank Enterprise Award (BEA) Program, which encourages insured depository institutions to engage in eligible development activities and to make equity investments in CDFIs. The Fund also administers the Presidential Awards for Excellence in Microenterprise Development, which recognize outstanding microenterprise development and support programs in an effort to advance an understanding of best practices in the field of domestic microenterprise development.

The Fund's regulatory priority for fiscal year 2001 is to continue to streamline the application and review processes for the BEA Program.

TREAS

PROPOSED RULE STAGE

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106. REVISION OF BREWERY REGULATIONS AND ISSUANCE OF REGULATIONS FOR TAVERNS ON BREWERY PREMISES (BREWPUBS)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

26 USC 5051 to 5056; 26 USC 5401 to 5417; 27 USC 205

CFR Citation:

27 CFR 7; 27 CFR 25

Legal Deadline:

None

Abstract:

ATF intends to streamline regulations applying to breweries. ATF will eliminate obsolete regulatory provisions. A formula system for manufactured beer products will replace statements of process attached to the brewers notice. The annual notice for small brewers to pay the reduced rate of tax will be eliminated. Separate regulations for brewpubs will be added to part 25. A section will be added to part 25 to authorize and regulate the alternating use of brewery premises by different brewers. Regulations authorizing the operation of brew-on-premises facilities will be added to part 25.

Statement of Need:

ATF intends to streamline its regulations applying to the brewing industry. These changes will simplify brewery reports and operations and eliminate obsolete regulatory provisions. Specific changes would include the implementation of a formula system for the breweries to replace the statement of process; the establishment of a separate subpart containing simplified regulations for brewpubs; authorizing alternating brewery premises among different proprietors; eliminating the annual notice to pay the reduced rate of tax for most breweries; authorizing brewers to file the Brewer's Report of Operations on a quarterly basis; and authorizing many brewers to take inventories quarterly rather than monthly. The rule will also propose minimum production standards for beer thereby reducing formula filings and a revised statement of net contents requirement for certain container sizes.

Summary of Legal Basis:

ATF has undertaken this review of brewery regulations as part of the President's Regulatory Initiative. These regulations are issued under the general authority of the Secretary of the Treasury to promulgate regulations to implement the Internal Revenue Code and the Federal Alcohol Administration Act.

Alternatives:

Not applicable. ATF believes that industry will support these regulatory changes because they will streamline regulatory requirements applying to the brewing industry.

Anticipated Cost and Benefits:

The proposed regulations will benefit the brewing industry by reducing required inventories, notices, and other submissions to ATF.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

William Foster
Program Manager
Department of the Treasury
Bureau of Alcohol, Tobacco and Firearms
650 Massachusetts Avenue NW.
Washington, DC 20226
Phone: 202 927-8210

RIN: 1512–AB37

TREAS

107. COMMERCE IN EXPLOSIVES (INCLUDING EXPLOSIVES IN THE FIREWORKS INDUSTRY)

Priority:

Other Significant

Legal Authority:

5 USC 552(a); 31 USC 9303 to 9304; 40 USC 304(k); 18 USC 847; 18 USC 921 to 930; 18 USC 1261; 19 USC 1612 to 1613; 19 USC 1618; 26 USC 7101; 26 USC 7322 to 7326; 31 USC 9301

CFR Citation:

27 CFR 55

Legal Deadline:

None

Abstract:

Pursuant to section 610 of the Regulatory Flexibility Act, ATF published a notice on January 10, 1997, seeking public comments on whether it should revise its regulations, codified at 27 CFR part 55, governing Commerce in Explosives (Including Explosives in the Fireworks Industry). Based on

comments received, ATF plans to initiate a rulemaking to revise these regulations in 2001.

Statement of Need:

This notice of proposed rulemaking will address many of the issues in part 55, Commerce in Explosives, especially the issues in requirements for explosives, including fireworks explosive materials. Pursuant to the periodic review requirements of the Regulatory Flexibility Act (5 U.S.C. 610), ATF published on January 10, 1997 a General Notice initiating the review of a final rule published in 1990 concerning the storage of fireworks explosives materials. The 1990 rule, which was issued as a result of the number and severity of explosions occurring on the premises of special fireworks plants, amended certain regulations codified at 27 CFR part 55, generally concerning the recordkeeping and storage of fireworks explosive materials. The regulations also codified two fireworks related rulings issued in 1979 and 1985, and the provisions of Public Law 99-308 relating to black powder. As a result of the public comments received in response to the General Notice and further study of this issue, ATF will issue a notice of proposed rulemaking covering this and related commerce and storage of explosives issues.

Summary of Legal Basis:

18 U.S.C. 847 grants the Secretary of the Treasury broad discretion to promulgate regulations necessary for the importation, manufacture, distribution, and safe storage of explosives materials. 18 U.S.C. 846 authorizes the Secretary to prescribe precautionary measures to prevent the recurrence of accidental explosions in which explosive materials were involved. The General Notice and upcoming notice of proposed rulemaking are also being issued pursuant to section 610 of the Regulatory Flexibility Act (5 U.S.C. 610), which requires an agency to review within 10 years of publication rules for which an agency prepared a final regulatory flexibility analysis addressing the impact of the rule on small businesses or other small entities.

Alternatives:

Alternatives will be examined in the context of public comments to the notice of proposed rulemaking.

Anticipated Cost and Benefits:

Unknown at this time.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
General Notice of Regulatory Review	01/10/97	62 FR 1386
NPRM	01/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

James Ficaretta
Program Manager
Department of the Treasury
Bureau of Alcohol, Tobacco and Firearms
650 Massachusetts Avenue NW.
Washington, DC 20226
Phone: 202 927-8210

RIN: 1512–AB48

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DEPARTMENT OF VETERANS AFFAIRS (VA)

Statement of Regulatory Priorities

The Department of Veterans Affairs (VA) administers benefit programs that recognize the important public obligations to those who served this Nation. VA's regulatory responsibility is almost solely confined to carrying out mandates of the laws enacted by Congress relating to programs for veterans and their beneficiaries. VA's major regulatory objective is to implement these laws with fairness, justice, and efficiency.

Most of the regulations issued by VA involve at least one of three VA components: The Veterans Benefits Administration, the Veterans Health Administration, and the National Cemetery Administration. The primary mission of the Veterans Benefits Administration is to provide high-quality and timely nonmedical benefits to eligible veterans and their beneficiaries. The primary mission of the Veterans Health Administration is to provide high-quality health care on a timely basis to eligible veterans through its system of medical centers, nursing homes, domiciliaries, and outpatient medical and dental facilities. The primary mission of the National Cemetery Administration is to bury eligible veterans, members of the Reserve components, and their dependents in VA National Cemeteries and to maintain those cemeteries as national shrines in perpetuity as a final tribute of a grateful Nation to honor the memory and service of those who served in the Armed Forces.

BILLING CODE 8320–01–S

ENVIRONMENTAL PROTECTION AGENCY (EPA)

Statement of Regulatory and Deregulatory Priorities

Meeting the Challenge of the 21st Century

In the thirty years since the formation of EPA, the United States has made steady progress in cleaning up our water, air, and land. Though serious challenges remain, a remarkable national consensus has fueled continuous efforts throughout our society to protect the environment despite the growing stress we have placed upon it through rapid population growth and unprecedented economic expansion. Much of this success is attributable to the system of Federal and State regulation that has directed and coordinated private investment in pollution control and prevention. Indeed, EPA is known foremost as a regulatory agency because of its historic reliance on this most visible tool, and the document before you lays out the key regulatory actions in the coming year that will address the most significant environmental problems, and, in some instances, require substantial investment.

But while regulation will certainly remain at the core of American environmental policy in the foreseeable future, EPA has learned that we cannot consider ourselves merely a regulatory agency if we are to be what the public expects and requires, the principal administrator for environmental protection in our society. Instead, in the twenty-first century EPA must increasingly act as an innovator, educator, and leader in managing a broad set of new tools – including new methods to design and administer regulations – that engage all segments of our society in enlightened behaviors that protect the environment while promoting appropriate economic growth.

Both the President and Vice President have called for a government that works better and costs less, and EPA has been hard at work to meet that challenge. Under Administrator Browner, EPA has been working to make regulations cheaper, cleaner, and smarter in order to produce important environmental improvements at lower cost for the American people. We have been enhancing our partnerships with States, Tribes, and industry to place decisionmaking responsibility where it will best balance the twin goals of national consistency and local responsiveness. And we have been expanding the power of individuals to recognize and respond to environmental challenges in their own communities.

Cheaper, Cleaner, Smarter Regulation

Because of EPA innovations during the past decade, the environment is cleaner – with less pollution of the Nation's air, water, and land. Some regulations are cheaper – with lower costs associated with environmental protection. Environmental management is smarter – experimenting with better means to solve existing and emerging environmental problems. Improvements are apparent in regulatory programs where we've introduced more flexibility, reduced costs, and made it easier for businesses to understand and comply with requirements.

Cleanup of Superfund sites is now faster, fairer, and less expensive. As a result of administrative reforms that began in 1995, the average time and costs associated with cleanup have fallen by as much as 20 percent. Moreover, as much as $1.4 billion has been saved as a result of actions that make it possible to select and use the most efficient remedy for cleanup.

Brownfields – properties that have been abandoned or neglected because of real or perceived contamination problems – are being revitalized and returned to productive use. Cleanup and redevelopment are now underway at more than 300 sites. With seed money from EPA, communities have leveraged almost $2 billion in public and private sector investments, returned hundreds of properties to productive reuse, and created more than 6,000 jobs.

EPA is taking aggressive steps to address remaining threats to public health and the environment from air pollution. Recent regulations will ensure that a new generation of technology will soon be in place to control harmful emissions from motor vehicles and that the low-sulfur fuel needed to support new clean-air technology will be readily available. The Agency has accelerated its action to promulgate essential, industry-specific rules to control toxic air pollutants. And the Administrator has acted to protect children and asthma patients from the harmful effects of smog, even as we argue before the Supreme Court for the Agency's responsibility to provide even greater regulatory protection under the law.

In many respects, new clean air requirements are more flexible and less expensive than they would have been earlier in our history, and they yield better environmental results. Market-based trading has been successful in controlling acid rain: between 1990 and 1998, national sulfur dioxide emissions fell by more than 4 million tons; rainfall in the eastern United States is now about 25 percent less acidic, and some New England ecosystems show signs of recovery. Recently, the Chicago Board of Trade announced the sale of sulfur dioxide credits had realized $25 million in proceeds, meaning that companies purchasing these credits were realizing impressive savings from the transactions, even while emissions contributing to acid rain formation were being reduced nationally. EPA's acid rain program has also been successful at reducing emissions of nitrogen oxide, the prime ingredient in smog formation. NOx emissions from electric utilities affected by the program have dropped 35 percent.

Working to keep up with population growth and economic expansion means that we need to constantly adapt our strategies to achieve needed results. Despite great progress in controlling point sources of pollution over thirty years, more than a third of American waterways assessed by States are still too dirty for fishing and swimming. Runoff from agricultural lands and urban areas remains the primary source of the leading pollutants: siltation, bacteria, the nutrients phosphorus and nitrogen, and metals. To address this need, EPA is working to integrate water quality permitting, monitoring, and reporting into broader strategies that focus on individual watersheds, a move that brings greater efficiency, more attention to local priorities, and better understanding of local conditions. Today, all 50 States, six territories, and 80 tribal governments have completed comprehensive watershed assessments, creating the first coordinated overview of water quality priorities in the Nation's history.

The way we prepare and implement new rules may be as important as the rules themselves. For instance, under Administrator Browner, EPA has emphasized the protection of children, who may frequently be more vulnerable to environmental contaminants than their parents, in all our program areas. In 1998 the Vice President called for a bold new initiative to assess toxic characteristics of hundreds of chemicals, particularly as to their effects on children. And just recently EPA completed an agreement with the manufacturer of Dursban, the most widely used household pesticide product in the United States, to

eliminate it from the market for nearly all household purposes. The action was designed in part to significantly reduce residues of the active ingredient chlorphyrifos on several foods that children eat routinely.

EPA has also stepped up its traditionally aggressive outreach to small businesses and communities subject to our rules. The Agency recognizes that these small entities often lack the resources or sophistication of their larger counterparts to comply with complex and expensive regulations. EPA routinely considers the potential impact of its rules on small entities and seeks to minimize unnecessary burden on those parties, while still meeting the requirements of the environmental statute. Working with the Small Business Administration and the Office of Management and Budget, EPA has conducted more than 20 Small Business Advocacy Review Panels under the Regulatory Flexibility Act (RFA). On those more frequent occasions when the Panel provision is not invoked, EPA has still found myriad ways to simplify rules for small parties.

Related to the effort to write cheaper, cleaner, smarter rules, is the need to ensure that people subject to them understand and carry out their responsibilities. To that end, EPA is writing its new regulations in an easy-to-understand, reader-friendly format known as Plain Language. New compliance assistance programs and incentives complement EPA's traditionally strong environmental enforcement. Environmental managers in different business sectors, local governments, and Federal agencies can now find information on environmental requirements and pollution prevention by going online to Web-based compliance assistance centers. During the past four years, 670 companies have identified potential environmental violations at more than 2,700 facilities – voluntarily – based on EPA's offer to reduce or eliminate penalties for facilities that routinely audit their operations, disclose violations, and quickly correct problems.

Partnerships for Better Results

EPA has broadened its impact and effectiveness by working in partnership with public and private sectors. Today, more than ever, EPA recognizes that it must involve everyone – other government agencies, businesses, communities, and individuals – to meet environmental goals.

The National Environmental Performance Partnership system, established in 1995, gives States and EPA a more flexible process for setting priorities, clarifying responsibilities, and making the most effective use of taxpayer dollars. Forty States have signed partnership agreements, and 44 States have opted to consolidate EPA grants. In 1997 we reached agreement with the States on how they can pursue innovations while maintaining the nationwide protection provided by Federal environmental standards. EPA's partnership with States is rapidly expanding our national capability to oversee environmental improvement, with States taking on an increasing share of the responsibility for environmental action. Today, States have assumed authority for approximately 70 percent of the EPA programs eligible for delegation. Further, States now conduct about 75 percent of all enforcement actions taken by State and Federal government combined. The EPA-State partnership has come of age, with EPA providing policy and technical leadership, while States carry out the lion's share of the daily work of environmental protection.

EPA and business are working better together based on a growing realization that environmental and economic performance can go hand-in-hand. Today, more than 7,000 organizations participate in one or more of EPA's voluntary partnership programs. Along with significant environmental benefits, annual savings for participants are estimated at $3.3 billion. Some of America's most well known corporations, along with smaller, innovative organizations, are using the flexibility in Project XL to test alternatives to the current regulatory system. Under Project XL, which stands for eXcellence and Leadership, businesses enter into a formal agreement to meet a level of environmental performance beyond current requirements in exchange for procedural flexibility not otherwise available under rule or permit. Today, 50 projects are underway, all of which have potential for more efficient and effective environmental management.

One example of how Project XL works is the Final Project Agreement (FPA) with Lucent Technologies, which will afford the company substantial permit flexibility in return for superior environmental performance and systematic improvements that may be applicable elsewhere. This FPA defines a five-year experiment to test whether, over time, a high-quality Environmental Management System (EMS) can generate a single governing environmental document for use in the microelectronics industry that delivers superior environmental performance, allows environmental managers and the public a clearer, better understanding of the environmental management program, and achieves a more efficient interaction with environmental policy than the traditional environmental permitting system affords. The FPA allows Lucent to use its EMS as a framework for developing specific proposals to simplify permitting, record keeping, and reporting requirements, while driving continual improvement and pollution-prevention programs. The FPA provides a ''test bed'' for the use of a high-quality EMS for determining and managing regulatory flexibility while achieving superior environmental performance.

Based on these and other partnership experiences, industry representatives are now working with EPA to introduce another innovative program, called the National Environmental Performance Track, to encourage, recognize, and reward environmental stewardship. EPA has offered to endorse companies which exceed minimum regulatory requirements and take extra steps to reduce and prevent pollution. Performance Track is intended for top-performing facilities and companies with a proven record of regulatory compliance, an operational Environmental Management System, and a demonstrated commitment to continued environmental improvement and outreach to the local community and the public. The program has two tiers, the first of which is already in operation. The National Achievement Track rewards facilities that have a strong compliance record and have raised the bar by setting up an Environmental Management System, voluntarily reducing pollution, and making commitments to further environmental improvement. The National Environmental Stewardship track, which is still being developed, will move the bar even higher with a corporate commitment for stronger environmental improvement throughout its operations. Benefits for participants include national recognition, regulatory and administrative flexibility, a more cooperative relationship with EPA, a reduction in both record keeping and reporting requirements, and flexibility in meeting certain regulatory requirements.

EPA is providing leadership to help communities grow and prosper in ways that preserve environmental quality. Through involvement in the national

Smart Growth Network and other initiatives, we provide technical tools and information that allow communities to understand the environmental consequences of growth. This is critical assistance at a time when the nation's forests, crop lands, and other open spaces are being lost to development at an alarming rate.

We are working more effectively with other Federal agencies, pooling our resources, and making best use of our respective strengths to address a number of national priorities, including protecting children's health. Through a combined strategy of research, public education, and regulatory action, we have made significant strides in reducing risks for some of society's most vulnerable populations.

A Stronger Public Role

Well informed citizens who are actively involved in environmental decisions are a powerful new force in achieving environmental results. Increasingly, Americans are getting involved in environmental issues, and it's clear they want a say in decisions that affect them. But to participate effectively, they need high-quality information that they can understand and use. They need access to decision-makers and opportunities to express their views.

Today, EPA is using new technology to improve the quality of environmental information and make it easier to obtain. After just a little over five years of operation, EPA's site on the World Wide Web is now receiving over 70 million hits each month – which involves the display of over 15 million Web pages – typically at the request of members of the public seeking access to a rich assortment of national and community-level data and other descriptive information. We also routinely involve the public in our work – gathering data, developing new regulations and standards, and experimenting with new ideas.

To meet Clean Air Act deadlines for developing control standards for 174 categories of toxic air pollution sources, EPA turned to the industries to be regulated and other interested parties to gather data and consider appropriate action. This move reduced the time and costs of developing the standards, laying the groundwork for faster, smoother implementation. The Common Sense Initiative was one of our broadest and most ambitious experiments in public participation. Representatives from industry, State and local government, and citizen-supported environmental groups came together to identify ways of making environmental protection more efficient and effective for all parties. The experiment resulted in regulatory changes, greater experience with public participation processes, and in one industry – metal finishing – a model for environmental stewardship that goes far beyond what is required by law. Sector-based approaches are now being considered for other industry groupings.

EPA supported the public's right to know about environmental conditions by significantly expanding the national Toxics Release Inventory. A new rule described in this Regulatory Plan will ensure that communities know whether and how much lead is being released in their vicinity. Citizens now have more information about releases of toxic emissions in their communities, which provides incentives for facilities to drive their emissions down. Between 1988 and 1998, at the same time that TRI required reporting on chemical releases, national air releases declined by 58 percent, and water releases declined by 73 percent. Over the same period 29 percent less waste was injected underground nationwide, while facilities disposed of 24 percent less waste on-site, and increased off-site disposal by just a half percent. The numbers of facilities and kinds of chemicals subject to TRI have changed over time, but there can be little doubt that heightened awareness, by both industry and the public, of chemicals in our midst has caused nationwide releases of reported chemical releases to decline dramatically since the TRI was established.

The Challenges Ahead

The actions listed in today's Regulatory Plan are designed to meet the environmental problems of today and tomorrow. They address the challenge of residual pollution of our water, air, and land, and the ubiquity of toxic chemicals in our environment. They represent part of the foundation of a new generation of environmental protection for the people and natural resources of the United States. EPA will continue to explore and introduce new ways of preparing cheaper, cleaner, smarter regulations, of forming effective partnerships in a broad, societal effort to protect ourselves and our children, and of involving citizens in understanding and representing their crucial stake in a clean environment in their own communities.

Highlights of EPA's Regulatory Plan for 2000

EPA's regulatory plan for 2000 reflects the Agency's continuing commitment to create new environmental protection strategies that better protect public health and the environment at lower cost.

Here are highlights of our upcoming rules:

Office of Air and Radiation Highlights

One of the most significant recent events for the Office of Air and Radiation (OAR) was an adverse court decision regarding EPA's air quality standards. As summarized below, EPA is appealing this decision, and is re-evaluating its implementation program while it awaits legal resolution of this situation. Meanwhile, EPA remains committed to taking advantage of the flexibility granted by the Clean Air Act that enables companies, States, and communities to meet clean air goals with low-cost approaches. The following paragraphs summarize the most significant of OAR's activities.

- In 1997, EPA established new, more stringent air quality standards for ozone and particulate matter based on new scientific and technical information. The new standards were designed to offer increased protection for public health and the environment, and EPA began pursuing a commonsense implementation strategy that would give States and industry flexibility with which they can meet these air quality goals. However, on May 14, 1999, a three-judge panel of the D.C. Circuit found that the Clean Air Act provision authorizing the new standards is unconstitutional as EPA applied it. This decision did not call into question the scientific basis for the new standards, only the procedure by which they were established. EPA has appealed this decision and intends to vigorously defend the standards in court. However, until the matter is resolved in court, EPA must defer to the panel's decision, and is re-evaluating this implementation strategy to decide which parts of it can continue and which parts must be put on hold during the litigation.
- To address the problem of ozone and nitrogen oxides (NOx) pollution blowing across State boundaries and interfering with clean-air attainment in other States, EPA is implementing a program of regional NOx control. Reductions from this program are scheduled to begin in May of 2003.

- To achieve further emission reductions mandated by the Clean Air Act, EPA is developing new standards for diesel engines. EPA has also proposed limitations on the sulfur content of diesel fuel available nationwide. Sulfur in diesel fuel has a detrimental impact on catalyst performance and could be a limiting factor in the introduction of advanced technologies on diesel engines.
- In accordance with Section 801 of the Energy Policy Act of 1992, EPA is developing health and safety standards for protection of the public from releases from radioactive materials stored or disposed of by the Department of Energy in the nuclear waste repository being constructed at Yucca Mountain in Nevada.
- The Agency has proposed changes to simplify and streamline the New Source Review Program, which requires newly built facilities or those undergoing major modification to obtain a permit to ensure that emissions will not cause or contribute to air pollution problems. A final rulemaking is expected late in 2000.
- EPA, building on successful State programs, has been working with stakeholders to develop a more streamlined way for facilities to get operating permit updates from State or local agencies. Depending on the environmental significance of the change, States would have greater flexibility to decide the appropriate amount of EPA and public review for most permit revisions.
- In August of 1997, EPA completed a comprehensive revision to streamline its regulations on transportation conformity. On March 2, 1999, the U.S. District Court for the District of Columbia overturned parts of that 1997 revision, including the provisions governing which projects can proceed without a conforming transportation plan and when States can use State Implementation Plans that EPA has not approved. The Administration's initial response to this court decision was to issue guidance from EPA and the Department of Transportation dealing with the issues in question. EPA is now developing a rule to respond to these court decisions that will formalize this guidance and deal definitively with all the issues raised by the court.
- To date, our air toxics program has focused primarily on getting broad emission reductions from large industrial sources through technology-based standards. Since 1990, EPA has issued standards affecting 77 different industries, such as petroleum refineries and chemical manufacturing plans. When fully implemented, these standards will reduce more than one million tons of toxic air emissions per year. Additionally, through other efforts such as the phase-out of lead in gasoline, we have significantly reduced air toxics from cars and trucks. We are continuing to set technology-based standards for large industries, and will complete more than 80 additional standards over the next few years. The rules listed in this year's Regulatory Plan — covering industrial boilers, institutional/commercial boilers, wood manufacturing, reciprocating engines, and combustion turbines — are among the most significant remaining categories to be regulated under this program. While working on these standards, we are beginning to evaluate those sources with standards already in place to determine if the remaining risk from these sources warrants additional regulation. We are also implementing our Urban Air Toxics Strategy, which focuses on 33 air toxics that pose the greatest risk in the largest number of urban areas and presents our plan, both nationally and more locally, to reduce those toxics. Finally, to better understand and measure risks from air toxics, we are also conducting important health research and improving our emissions inventories, modeling capability, and monitoring network.
- On May 22, 1996, EPA published its final decision not to revise the primary sulfur dioxide NAAQS. The notice stated that EPA would shortly propose a new implementation strategy to help States in addressing short-term peaks of sulfur dioxide. The new implementation strategy - the Intervention Level Program - was proposed on January 2, 1997. In July 1996, the American Lung Association and the Environmental Defense Fund petitioned the U.S. Court of Appeals for the D.C. Circuit for a judicial review of EPA's decision not to establish a new 5-minute NAAQS. On January 30, 1998, the court found that EPA did not adequately explain its decision and remanded the case so EPA could explain its rationale more fully. EPA published a schedule for responding to the remand in the May 5, 1998 **Federal Register**. Since that notice, EPA has continued to work on the proposed response to the remand by reviewing additional SO2 air quality information. EPA intends to publish an informational notice in the **Federal Register** by December 2000.

Office of Water Highlights

On August 6, 1996, President Clinton signed the Safe Drinking Water Act (SDWA) Amendments of 1996 which laid out requirements to strengthen the Nation's drinking water program. These amendments directed EPA to further improve the quality of drinking water and protect public health by requiring the following actions:

- On November 2, 1999, EPA published the proposed National Primary Drinking Water Regulation (NPDWR) for Radon that will reduce exposure to radon in homes. The regulation recognizes that the public health problem from radon in indoor air typically far exceeds the health risks of breathing radon released to the air from showers, sinks, or drinking water. The rule, therefore, lays out a unique framework that allows States and/or systems to adopt multimedia programs which reduce radon risks from indoor air and drinking water in combination. States and systems that choose this option will focus risk reduction on the greatest threat (indoor air), while spending much less money to comply with these rules than if they focused on drinking water alone.
- On May 10, 2000, EPA published the NPDWR for Ground Water that sets in place an increasingly targeted strategy to identify ground water systems that are vulnerable to microbial contamination. The multiple barrier approach, of this rule relies on 5 major components (inspections, source water monitoring, corrective action, treatment, and compliance monitoring) which, in combination, EPA believes strikes an appropriate balance between the intensity or burden of protective measures against microbial contamination and follow-up action to the risk being addressed.
- One June 22, 2000, EPA published the NPDWR for Arsenic which is another rule mandated by the 1996 SDWA Amendments. This rule will establish an enforceable maximum contaminant level (MCL) as close to the health based maximum level contaminant level goal as possible. Presently, the arsenic standard is 50 ug/l. The National Academy of Science, however, issued a report in March 1999 that urged EPA to lower the drinking water standard, based on conclusive evidence that inorganic arsenic causes bladder, lung and skin cancer in humans. EPA proposed an MCL of 5 ug/L for arsenic and

requested comment on MCL options of 3, 10, and 20 ug/L. EPA will consider comments received on the proposal and any additional data that may become available in order to decide what that appropriate level is, balancing health risk reduction benefits and the costs.

- EPA is also required to publish a Stage 2 Disinfectants/Disinfection Byproducts Rule which will reduce the potential health risks posed by disinfection byproducts (DBPs). The regulation, along with the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), is intended to expand existing public health protections and address concerns about risk trade-offs between pathogens and disinfection byproducts. Although the LT2ESWTR is not required, publishing these two rules together will help to ensure that drinking water utilities do not compromise adequate microbial protection while they take steps to control DBPs. In addition, the LT2ESWTR will develop monitoring requirements to identify systems at high risk for the pathogen *Cryptosporidium* (which is highly resistant to disinfection) and prescribe an appropriate level of additional treatment.

The Clean Water Act (CWA) requires EPA to establish effluent limitations guidelines and standards to regulate the quality of point source discharges. Pollution from concentrated animal feeding operations (CAFOs) potentially can reach waters of the United States through discharges from waste storage and animal confinement areas and from areas where waste is applied to the land as a nutrient or soil amendment. The potential for polluted discharges from these areas is especially high during periods of heavy rain when waste storage and disposal systems and the soil's assimilation capacity are likely to be overwhelmed. Discharges from CAFOs can lead to degradation of surface waters due to the addition of nutrients, metals, salts, BOD, various pathogens and other pollutants.

Currently, certain CAFOs are regulated through permits issued under the National Pollutant Discharge Elimination System (NPDES). These permits specify appropriate discharge standards based on either promulgated effluent limitations guidelines and/or permit writers' best professional judgment. EPA promulgated the regulations describing the NPDES regulatory process for CAFOs in 1976. It also promulgated effluent limitation guidelines applicable to feedlots in 1974 and 1975.

EPA is reexamining and plans to revise the existing NPDES and effluent guideline regulations related to CAFOs due to changes within the animal agriculture industry since the rules were promulgated in the 1970s; new animal and waste management techniques; improved understanding of the water quality impacts associated with CAFO waste management; and issues associated with implementing the existing regulations. The types of changes that are being considered, but may not necessarily be adopted, include requirements to develop and implement nutrient management plans; requirements regarding land application of manure; requirements regarding treatment of manure, litter and wastewater to reduce manure constituent concentrations; installation of controls to contain animal waste; Best Management Practices; additional sampling and monitoring, reporting and recordkeeping; and revising the regulatory scope.

Office of Prevention, Pesticides, and Toxic Substances

- The Food Quality Protection Act (FQPA) overhauled U.S. pesticides laws, enhancing protections related to pesticide residues in food by requiring aggregate and cumulative risk assessments, with a special emphasis on children and infants. EPA currently has underway the Pesticide Tolerance Reassessment Program, a ten year program to reevaluate the safety of all pesticide residues in food. Under this program, EPA has now completed reassessment of the first third of the pesticide residues in foods. Implementation of the Food Quality Protection Act has required an increase of the FIFRA Scientific Advisory Panel (FIFRA/SAP) activities. Significant risk assessment methodology issues continue to be addressed by the FIFRA/SAP. Methodology issues addressed by the FIFRA/SAP include drinking water assessment methodologies, approaches for conducting cumulative and aggregate risk assessments, use of 10x safety factors, and guidelines for assessing protein plant pesticides. The FIFRA/SAP also jointly sponsored with the Science Advisory Board several meetings on ethical considerations of the testing of human subjects.
- Because of the potentially serious consequences of human exposure to endocrine disrupting chemicals, Congress included specific language on endocrine disruption in the Food Quality Protection Act and amended Safe Drinking Water Act in 1996, mandating EPA to develop an endocrine disruptor screening program and to screen endocrine disruptors found in drinking water sources. A variety of chemicals are known to disrupt the endocrine systems of animals in laboratory studies, and compelling evidence has accumulated that endocrine systems of certain fish and wildlife have been affected by chemical contaminants, resulting in developmental abnormalities and reproductive impairment. The Endocrine Disruptor Screening Program focuses on providing methods and procedures to detect and characterize endocrine activity of pesticides, commercial chemicals, and environmental contaminants. While we do have extensive data – including some endocrine-related data – on pesticides, there currently is not enough scientific data available on most of the estimated 87,000 chemicals in commerce to allow us to evaluate all potential risks. The Endocrine Disruptor Screening Program will enable EPA to gather the information necessary to identify endocrine disruptors and take appropriate regulatory action. The Agency has established an Endocrine Disruptor Screening and Testing Program based on the recommendations of the advisory committee established by EPA to consider human health and ecological effects; and hormonal effects of pesticides, industrial chemicals and drinking water contaminants.
- In April 1998, a national initiative, known as the Chemical Right-To-Know (ChemRTK) Program, was announced in order to empower citizens with knowledge about the most widespread chemicals in commerce — chemicals that people may be exposed to in the places where they live, work, study, and play. EPA's ChemRTK Program is being designed in such a way as to make certain basic information about HPV chemicals available to the public. A major component of the Agency's ChemRTK activity is the *HPV Initiative*, which is a data collection and development program established by OPPTS for existing U.S. HPV chemicals. Under this Initiative, HPV chemicals are defined as organic chemicals manufactured (including imported) at or above 1 million pounds per year based on

information submitted under the 1990 TSCA Inventory Update Rule. Through the HPV Initiative, which includes a voluntary component (the HPV Challenge Program), certain international efforts, and rulemaking under TSCA such as this proposed rule, basic screening level hazard data necessary to provide critical information about the environmental fate and potential hazards associated with HPV chemicals will be collected or, where necessary, developed. Data collected and/or developed under the HPV Initiative will provide critical basic information about the environmental fate and potential hazards associated with these chemicals which, when combined with information about exposure and uses, will allow the Agency and others to evaluate and prioritize potential health and environmental effects and take appropriate follow up action.

- With almost a million children under 5 years of age with blood-lead levels exceeding the Center for Disease Control's level of concern (10 ug/dl), reducing the opportunities for childhood lead poisoning resulting from activities associated with lead-based paint activities continues to be a priority for the Agency. Elevated blood-lead levels can lead to reduced intelligence and neuro-behavioral problems in young children, and can cause other health problems in children and adults. EPA is working on a final regulation to replace the existing interim guidance that identifies lead-based paint, lead-contaminated dust, and lead-contaminated soil hazards. EPA is considering proposed approaches to address lead risks associated with renovation and remodeling activities. To help reduce the costs related to the abatement of lead-based paint hazards, EPA is working on final rules which would address the disposal of lead-based paint debris.
- EPA expects to finalize a rule which would require EPA-approved Pesticide Management Plans (PMPs) for certain pesticides that have a high groundwater contamination potential. Through a PMP, a State or tribe may commit to both EPA and the public that they will manage the use of a particular pesticide in a way that avoids unreasonable risks to groundwater that would otherwise warrant the cancellation of the use of that particular pesticide. The PMP program was developed in partnership with State and tribal representatives.

Office of Environmental Information Highlights

- The Chemical Right-to-Know Initiative, which was announced by the Vice President in April 1998, included a directive to the Agency to list and lower the reporting thresholds for persistent, bioaccumulative, toxic (PBT) chemicals reported under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). This information will better enable communities to understand the nature of toxic releases and potential risks at the local level, as well as establish local priorities. EPCRA section 313 currently requires reporting from facilities which manufacture or process at least 25,000 pounds of a listed chemical, or otherwise use 10,000 pounds of a listed chemical. These thresholds were initially established under the Emergency Planning and Community Right-To-Know Act (EPCRA) section 313(f)(1). Section 313(f)(2) of EPCRA gives the Administrator the power to establish a threshold amount for a toxic chemical different from the amount established by paragraph(1) and that such altered thresholds may be based on classes of chemicals. Since PBT chemicals persist in the environment and accumulate organisms, even small releases of PBT chemicals are of concern. Therefore, lower EPCRA section 313 reporting thresholds are appropriate for PBT chemicals
- In accord with the Vice President's directive, EPA has set out the criteria that will be used for determining if a chemical is persistent and bioaccumulative under EPCRA section 313 and has lowered the EPCRA section 313 reporting thresholds for certain PBT chemicals (64 FR 58666, October of 1999). EPA has also conducted an analysis to determine if lead and lead compounds meet the criteria for persistence and bioaccumulation and whether the EPCRA section 313 reporting thresholds should be lowered. On August 3, 1999 (64 FR 42222), EPA issued a proposed rule to lower the EPCRA.
- EPA is considering a proposal to address electronic reporting and record-keeping by regulated companies under all of EPA's environmental programs – air, water, hazardous waste, toxic substances, pesticides and emergency response. The Cross-Media Electronic Reporting and Record-keeping Rule (CROMERRR) would remove existing regulatory obstacles to electronic reporting or record-keeping under any of our programs, and it would set requirements for companies choosing to report and/or keep records electronically. In addition, the rule would set the conditions for allowing electronic reporting or record-keeping under State, tribal or local environmental programs that operate under EPA authorization or delegation.

Office of Solid Waste and Emergency Response Highlights

The Office of Solid Waste and Emergency Response (OSWER) is planning a number of actions to streamline, simplify, and ensure compliance under the Resource Conservation and Recovery Act (RCRA), the Federal law governing hazardous waste management. As part of its effort to refocus hazardous waste regulation on high-risk wastes, EPA is undertaking a number of actions to tailor standards to the nature or degree of risk posed by particular wastes.

- EPA is streamlining the regulation of listed hazardous wastes. Certain regulations are overly broad in that they apply regardless of the concentrations of the listed wastes. As a result, they regulate certain low-risk wastes (in particular, treatment residuals) as if they posed high risk. EPA's common-sense approach would exempt these low-risk wastes from the full management requirements designed for high-risk hazardous wastes.
- The Agency is considering revisions to the RCRA Hazardous Waste Manifest system to reduce the paperwork burden associated with the manifest. The chief goal of the manifest system is to facilitate the safe transportation of hazardous waste shipments to appropriate RCRA management facilities. Reduction in paperwork burden is part of the Administration's Regulatory Reinvention goal of cutting Government red tape. The Agency wants to standardize the manifest program across the states by introducing a truly uniform manifest tracking form that can be completed either manually or electronically.
- Radioactive wastes that are also hazardous wastes under RCRA are mixed wastes. The Agency is seeking to provide increased flexibility to facilities that manage low-level mixed waste (LLMW) and naturally occurring and/or accelerator-produced Radioactive Material (NARM) mixed with hazardous waste.

EPA is trying to reduce dual regulation of LLMW, which is subject to the Resource Conservation and Recovery Act (RCRA) and to the Atomic Energy Act (AEA). On November 19, 1999, EPA published a proposed rule that would lower cost and reduce paperwork burden, while improving or maintaining protection of human health (including worker exposure to radiation) and the environment. The Agency is seeking to allow on-site storage and treatment of these wastes at the generator's site. The use of tanks/containers to solidify, neutralize, or otherwise stabilize the waste would be required and would apply only to generators of low-level mixed waste who are licensed by the Nuclear Regulatory Commission (NRC) or an Agreement State. The Agency is also seeking to exempt LLMW and hazardous NARM waste from RCRA manifest, transportation, and disposal requirements when certain conditions are met. Under this conditional exemption, generators and treaters must still comply with manifest, transport, and disposal requirements under the NRC (or NRC-Agreement State) regulations for these types of wastes.

- Over the past several years, the Agency has worked with stakeholders from state agencies, industry, and the environmental community to develop recommendations to improve the Agency's permitting programs. These stakeholders concluded that permitting activities should be commensurate with the complexity of the activity and that permit programs should be flexible enough to allow streamlined procedures for routine permitting activities. The stakeholders recommended that regulations be developed to allow standardized permits for on-site storage and non-thermal treatment of hazardous waste in tanks, containers, and containment buildings. As a result of this recommendation, the Agency is considering revisions to the RCRA regulations to allow this type of permit.
- On April 25, 2000, EPA issued a regulatory determination to retain an exemption from hazardous waste management for fossil fuel combustion wastes. The utility industry has made significant improvements in its waste management practices over recent years, and most State regulatory programs are similarly improving. Nevertheless, coal combustion wastes could pose risks to human health and the environment if they are not properly managed. There is sufficient evidence that adequate controls may not be in place. For example, while most States can now require newer waste management units that accept coal combustion wastes to include liners and groundwater monitoring, 62 percent of existing utility surface impoundments (a type of waste management unit) do not have groundwater monitoring. EPA acknowledges that some waste management units may not warrant liners, depending on site-specific characteristics. To address those circumstances that warrant further environmental controls, the Agency is looking into developing and issuing appropriate RCRA subtitle D standards for the management of coal combustion wastes in landfills and surface impoundments that are generated by the electric power producers, including electric utilities and independent power producers.

Office of Administration and Resources Management Highlights

In 1995, EPA and the States agreed to develop and carry out the National Environmental Performance Partnership System (NEPPS) to: Promote joint planning and priority setting by EPA and the States; give States greater flexibility to direct resources where they need them most; foster use of integrated and innovative strategies for solving water, air, and waste problems; achieve a better balance in the use of environmental indicators and traditional activity measures for managing programs; and improve public understanding of environmental conditions and the strategies being used to address them.

EPA is announcing its intent to publish two new subparts under 40 CFR part 35. The first subpart governs Environmental Program Grants to States, Interstate, and Local Agencies (40 CFR 35, subpart A) and includes rules applicable to the Performance Partnership Grant (PPG) program. The second subpart contains Tribal-specific provisions for environmental program grants and a new Performance Partnership Grant (PPG) program for Tribes and Intertribal Consortia (40 CFR 35, subpart B). Under the PPG program, eligible applicants can combine environmental program grants into a single grant in order to improve environmental performance, increase programmatic flexibility, and achieve administrative savings. The proposed rules were published in the **Federal Register** on July 23, 1999. The Agency anticipates that the regulations will be made final in January 2001.

Office of Policy, Economics, and Innovations Highlights

The National Environmental Performance Track Program is being implemented initially with the Achievement Track program. In order to attract a large number of higher-performing facilities from various industry sectors, EPA has designed a variety of incentives. These include actions which recognize and highlight the achievements of the facilities that successfully fulfill the requirements for entry, but also include other incentives. Some of those incentives are being implemented by administrative actions, but others will require changes in existing Federal regulations. OPEI has convened an Agency work group to develop the rulemaking changes required. One part of this is changes in the regulations specifying reporting by facilities covered by the MACT provisions of the Clean Air Act. Facilities meeting the criteria for membership in Achievement Track would be eligible for reduced reporting and some other provisions, and facilities that more than meet goals for emissions reductions under MACT via pollution prevention means would qualify for some additional reduced reporting. A second part of the rulemaking will be reductions in reporting requirements for publicly owned treatment works (POTWs), under the Clean Water Act. A third would allow POTWs to notify the public of any violations of permits by the indirect dischargers using the POTWs' services by placing notices on the internet (rather than using paid newspaper advertisements). The last part of the rulemaking would be a pilot test of consolidated reporting (an idea explored extensively in the past several years). This is likely to begin with one or two industry sectors, and to be modeled on pilot efforts explored in EPA's Common Sense Initiative, and is likely to roll various periodic reports required under CAA, CWA, RCRA, and other statutes into one report, eliminating duplicate reporting and other difficulties. If this test is successful, EPA will consider widening the applicability to Achievement Track facilities in other industry sectors.

Summary

In developing all of these actions, EPA is committed to flexible, cost-effective regulatory programs that offer increased protections for public health and the environment. EPA welcomes

suggestions from the public to help the Agency in this effort.

EPA

PRERULE STAGE

108. CHEMICAL RIGHT-TO-KNOW INITIATIVE - HIGH PRODUCTION VOLUME (HPV) CHEMICALS

Priority:

Other Significant

Legal Authority:

15 USC 4 TSCA; 15 USC 8 TSCA; 42 USC 313 TRI; 7 USC 136 FIFRA

CFR Citation:

40 CFR 700 et seq

Legal Deadline:

Other, Judicial, December 31, 1999, Final Actions must be completed by 12/31/99.

Abstract:

The Chemical RTK Initiative was announced by the Vice President on EPA's Earth Day 1998 in response to the finding that most commercial chemicals have very little, if any, publicly available toxicity information on which to make sound judgments about potential risks. There are three key components to this initiative, each of which is being implemented by EPA. These are: collecting and making public screening level toxicity data for 2,800 widely used commercial chemicals; additional health effects testing for chemicals to which children are substantially exposed; and the listing and lowering of thresholds for persistent, bioaccumulative, toxic chemicals reported to TRI. This initiative will involve several separate activities, with any regulatory related actions included as separate entries in the regulatory agenda.

Statement of Need:

The Chemical Right-to-Know Initiative grew out of the finding of an EPA study that there is very little basic publicly available information on the health and environmental effects of even the most widely used commercial chemicals. Less than 7 percent of the 2,800 high production volume chemicals have a full set of baseline testing information readily available, while almost 50 percent have no public information whatsoever. The Chemical Right-to-Know Initiative is designed to close these information gaps, and to make both new and existing information available to the public.

Summary of Legal Basis:

To the extent that rulemaking is required to implement the Chemical Right-to-Know Initiative, EPA will utilize the testing authorities available under TSCA and the chemical reporting authorities of EPCRA section 313 (the Toxics Release Inventory).

Alternatives:

The Chemical Right-to-Know Initiative will rely on a combination of partnership programs and rulewriting to accomplish its goals. For instance, an HPV Challenge Program will ask industry to voluntarily provide both new and existing data on high production volume chemicals, while an HPV test rule would require testing of specific HPV chemicals of concern.

Anticipated Cost and Benefits:

The benefits of the Chemical Right-to-Know Initiative are substantial, as no one in the environmental community — whether in industry, government or the public — can make reasoned risk management decisions in the absence of reliable health and environmental information. The cost of baseline testing is well established, and runs about $200,000 per chemical for a full set of tests, for those chemicals on which data do not already exist. More detailed testing, as envisioned for the Children's Health testing portion of this initiative, may be more expensive, but has not yet been costed out.

Risks:

None.

Timetable:

Action	Date	FR Cite
Notice - HPV Initiative Completed - HPV Data To Be Received by 06/2005	10/00/00 06/00/05	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal

Additional Information:

SAN No. 4176

This initiative includes the following regulatory agenda activities: TRI's Reporting Threshold Rule (SAN 3880; RIN 2070-AD09); Test Rule; Multi-Chemicals Test Rule for High Production Volume Chemicals (SAN 3990; RIN 2070-AD16); Children's Health Test Initiative (SAN 2865; RIN 2070-AC27).

Sectors Affected:

32411 Petroleum Refineries; 325 Chemical Manufacturing

Agency Contact:

Mary Dominiak
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7405
Washington, DC 20460
Phone: 202 260-7768
Fax: 202 260-1096
Email: dominiak.mary@epa.gov

Barbara Leczynski
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7405
Washington, DC 20460
Phone: 202 260-3945
Fax: 202 260-1096
Email: leczynski.barbara@epa.gov

RIN: 2070–AD25

EPA

PROPOSED RULE STAGE

109. ● REGULATORY INCENTIVES FOR THE NATIONAL ENVIRONMENTAL ACHIEVEMENT TRACK PROGRAM

Priority:

Other Significant

Legal Authority:

Not Yet Determined

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

The National Environmental Achievement Track is designed to recognize facilities that consistently meet their legal requirements and have implemented high-quality environmental management systems, and to encourage them to achieve more by continuously improving their environmental performance and

informing and involving the public. Facilities gain entrance to Achievement Track by submitting an application that documents that four specific criteria are met. To promote participation in the program and the environmental and other benefits that will come with it, EPA intends to offer several incentives. Among those incentives are the adjustments in current regulatory requirements that are the subjects of this rulemaking. These include reducing the frequency of reports required under the Maximum Achievable Control Technology (MACT) provisions of the Clean Air Act; streamlined by publically owned treatment works (POTWs) under the Clean Water Act; and opportunity for Achievement Track facilities to consolidate reporting under various environmental statutes into a single report.

Statement of Need:

The Administrator of EPA has announced the National Environmental Performance Track Program, of which the Achievement Track program is the first element to be implemented. By identifying facilities that have better environmental performance than others, and by requiring them to commit to goals for sustained improvements, EPA expects the environment to greatly benefit. Facilities that are able to qualify for the program will make a public commitment to reducing specific aspects of their impacts on the environment, and the program is likely to induce other facilities to make changes in their operations that will bring about analogous reductions in their environmental impacts. In order to attract significant numbers of facilities, Achievement Track will provide incentives for joining, in the form of substantial benefits to the facilities that qualify. EPA is considering alterations in reporting and other requirements (to be available only to Achievement Track facilities) that would be made available as a result of this rulemaking. Extensive input (written comments and several public meetings) from stakeholders has convinced EPA that benefits such as these are crucial to achieving the intended environmental benefits of the Achievement Track program.

Summary of Legal Basis:

All of the modifications under consideration are modifications of existing regulations, promulgated over the past several years under statutes that include the CAA, CWA, EPCRA, SDWA, and others. Within these statutes, EPA has discretion to set reporting frequencies, the contents of reports, monitoring, and other specifics, based on an assessment of the need for information to implement the statutes.

Alternatives:

Deliberations within the Agency, and among stakeholders and EPA, have convinced EPA that a full and robust set of incentives is crucial to the successful implementation of Achievement Track. EPA developed a list of over forty different candidate incentives, and discussed many of these during a set of public meetings held during the design phase of the National Environmental Performance Track. Several incentives can be implemented through EPA administrative actions, but some potential incentives would require changes in existing regulations. The specific incentives being considered here resulted from intense analysis and debate within EPA and the Administrator's judgment that they contribute to achieving the program's aims. During the rulemaking process, EPA will consider various alternatives for these incentives, ranging from substantial changes in reporting frequency and content to no changes. EPA is also considering initiating rulemaking on other incentives beyond the ones discussed here.

Anticipated Cost and Benefits:

Overall, EPA expects there to be a net reduction in compliance costs for facilities that participate in Achievement Track. Facilities would have direct reductions in the efforts required to collect, summarize and report various data elements, and would potentially benefit from a streamlining of their environmental reporting information systems and from an integration of those data systems into company environmental management systems. EPA and some State regulatory authorities are likely to see modest increases in workload (and therefore in costs), mostly in the revising permits. This effect would be moderated by the fact that only a fraction of regulated facilities are expected to qualify for Achievement Track. Finally, because Achievement Track is designed to induce environmental improvements among those facilities that seek and obtain entrance to the program, EPA anticipates tangible environmental benefits to be realized.

Risks:

The risks of the intended rulemaking appear minimal. The criteria and the screening process for Achievement Track will identify and admit only facilities that operate significantly above the norm of other facilities. Because facilities must carry out their Achievement Track actions in the public spotlight, and because EPA expects that facilities will strive to stay qualified for the program, there is only a very small likelihood that mistakes would be made, and any such mistakes could easily be reversed. The actions being contemplated in this rulemaking entail mostly reporting changes, not substantive changes in permitted release rates or other actions that would directly impinge on the environment. All of these factors serve to limit the risks to the environment from the intended rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

State

Federalism:

Undetermined

Additional Information:

SAN No. 4473

Agency Contact:

Frederick W. Talcott
Environmental Protection Agency
Office of the Administrator
2129
Washington, DC 20460
Phone: 202 260-2768
Fax: 202 401-3998
Email: talcott.fred@epa.gov

Daniel J. Fiorino
Environmental Protection Agency
Office of the Administrator
2129
Phone: 202 260-2749
Fax: 202 401-3998
Email: fiorino.dan@epa.gov

RIN: 2090–AA13

EPA

110. NAAQS: SULFUR DIOXIDE (RESPONSE TO REMAND)

Priority:

Other Significant

Legal Authority:

42 USC 7409 CAA sec 109

CFR Citation:

40 CFR 50.4; 40 CFR 50.5

Legal Deadline:

Final, Judicial, December 31, 2000.

Abstract:

On November 15, 1994, the Environmental Protection Agency (EPA) proposed not to revise the existing 24-hour and annual primary standards. The EPA sought public comment on the need to adopt additional regulatory measures to address the health risk to asthmatic individuals posed by short-term peak sulfur dioxide exposure. On March 7, 1995, EPA proposed implementation strategies for reducing short-term high concentrations of sulfur dioxide emissions in the ambient air. On May 22, 1996, EPA published its final decision not to revise the primary sulfur dioxide NAAQS. The notice stated that EPA would shortly propose a new implementation strategy to assist States in addressing short-term peaks of sulfur dioxide. The new implementation strategy - the Intervention Level Program - was proposed on January 2, 1997. In July 1996, the American Lung Association and the Environmental Defense Fund petitioned the U.S. Court of Appeals for the D.C. Circuit for a judicial review of EPA's decision not to establish a new five-minute NAAQS. On January 30, 1998, the court found that EPA did not adequately explain its decision and remanded the case so EPA could explain its rationale more fully. EPA published a schedule for responding to the remand in the May 5, 1998 Federal Register. Since that notice, EPA has continued to work on the proposed response to the remand by reviewing additional SO2 air quality information. EPA intends to publish an informational notice in the Federal Register by December 2000.

Statement of Need:

Brief exposures to elevated concentrations of sulfur dioxide, while at exercise, may cause bronchoconstriction, sometimes accompanied by symptoms (coughing, wheezing, and shortness of breath), in mild to moderate asthmatic individuals. The existing sulfur dioxide National Ambient Air Quality Standard (NAAQS) provides substantial protection against short-term peak sulfur dioxide levels. At issue is whether additional measures are needed to further reduce the health risk to asthmatic individuals.

Summary of Legal Basis:

Title I of the Clean Air Act.

Alternatives:

The March 7, 1995, proposal notice sought public comment on three alternatives to further reduce the public health risk to asthmatic individuals posed by short-term peak sulfur dioxide exposures. These included: (a) a new 5-minute NAAQS; (b) a new program under section 303 of the Act; and (c) a targeted monitoring program to ensure sources likely to cause or contribute to high 5-minute peaks are in attainment with the existing standard. The January 2, 1997, notice proposed an alternative program under section 303 of the Act that will assist States in addressing high 5-minute peaks.

Anticipated Cost and Benefits:

A draft regulatory impact analysis was completed and made available for public comment at the time of the January 2, 1997 proposal.

Risks:

Exposure analyses indicate from the national perspective that the likelihood of exposure to high 5-minute sulfur dioxide concentrations is very low. Asthmatic individuals in the vicinity of certain sources or source categories, however, may be at higher risk of exposure than the population as a whole.

Timetable:

Action	Date	FR Cite
NPRM - NAAQS Review	11/15/94	59 FR 58958
NPRM - NAAQS Implementation (Part 51)	03/07/95	60 FR 12492
Final Rule - NAAQS Review	05/22/96	61 FR 25566
NPRM - Revised NAAQS Implementation (Part 51)	01/02/97	62 FR 210
Notice - Schedule for Response to NAAQS Remand	05/05/98	63 FR 24782
Notice - Informational FR Notice	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local

Federalism:

Undetermined

Additional Information:

SAN No. 1002

Agency Contact:

Gary Blais (Implementation)
Environmental Protection Agency
Air and Radiation
MD-15
Research Triangle Park, NC 27711
Phone: 919 541-3223
Email: blais.gary@epa.gov

Susan Stone
Environmental Protection Agency
Air and Radiation
MD-15
Research Triangle Park, NC 27711
Phone: 919 541-1146
Fax: 919 541-0237
Email: stone.susan@epa.gov

RIN: 2060–AA61

EPA

111. NEW SOURCE REVIEW (NSR) IMPROVEMENT

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

CAA as amended, title I

CFR Citation:

40 CFR 51.160 to 51.166; 40 CFR 52.21; 40 CFR 52.24

Legal Deadline:

None

Abstract:

This action is to revise the CAA new source review (NSR) regulations, which govern the preconstruction air quality review and permitting programs that are implemented by States and the Federal Government for new and

modified major stationary sources of air pollution. This rulemaking will deregulate, that is, exclude from major NSR program requirements, those activities of sources that, with respect to air pollution, have little environmental impact. The rulemaking will encourage pollution control and pollution prevention projects at existing sources. Control technology requirements will be clarified with respect to when and how they apply to sources that are covered. The action seeks to more clearly define the appropriate roles and requirements of sources, permitting authorities and Federal land managers and EPA in the protection of air-quality-related values in Federal Class I areas (i.e., certain national parks and wilderness areas) under the NSR regulations. State, local, and tribal permitting agencies will be given more flexibility to implement program requirements in a manner that meets their specific air quality management needs. Consequently, the rulemaking decreases the number of activities that are subject to NSR requirements and also expedites the permitting process for those sources that are subject to NSR. This action is designed to reduce the regulatory burden over all industries without respect to commercial size or capacity; therefore, it should have no detrimental impact on small businesses. This action also addresses several pending petitions for judicial review and administrative action pertaining to NSR applicability requirements and control technology review requirements. Regulations that will be affected are State implementation plan requirements for review of new sources and modifications to existing sources (40 CFR 51.160-166), the Federal prevention of significant deterioration program (40 CFR 52.21), and Federal restriction on new source construction (40 CFR 52.24). Finally, this NSR Improvement effort also includes a separate rulemaking (SAN 4390, NSR Improvement: Utility Sector Offramp Program), which will provide industries with the flexibility to focus more on existing pollution sources, with the goal of achieving as good or better environmental results than could be achieved by focusing strictly on new sources.

Statement of Need:

In August 1992, EPA voluntarily initiated a comprehensive effort to reform the NSR process. This effort was initiated to examine complaints from the regulated community that the current regulatory scheme is too complex, needlessly delays projects, and unduly restricts source flexibility. Currently there are no applicable statutory or judicial deadlines for the NSR reform rulemaking effort. The goal of this effort is to address industry's concerns without sacrificing the environmental benefits embodied in the present approach; that is, protecting and improving local air quality, and stimulating pollution prevention and advances in control technologies.

In July 1993, the New Source Review (NSR) Reform Subcommittee of the Clean Air Act Advisory Committee was formed. The Subcommittee's purpose is to provide independent advice and counsel to EPA on policy and technical issues associated with reforming the NSR rules. The Subcommittee was composed of representatives from industry, State/local air pollution control agencies, environmental organizations, EPA headquarters and regions, and other Federal agencies (National Park Service and Forest Service, Department of Energy, and the Office of Management and Budget).

Summary of Legal Basis:

There are no applicable statutory or judicial deadlines for the NSR reform rulemaking effort. However, the rule will address three outstanding settlement agreements: CMA Exhibit B, Top-down BACT, and the applicability test for modifications at utilities.

Alternatives:

The Subcommittee discussed numerous options for implementing NSR reform. However, EPA's primary focus has been to consider the specific recommendations developed by the Subcommittee and, where appropriate, use them in this rulemaking effort. In January 1996, EPA, as part of another regulatory streamlining measure, merged portions of a separate rulemaking to implement the 1990 CAA Amendments with the Reform effort. The combined package was proposed in the Federal Register on July 23, 1996. On July 24, 1998, EPA issued another Federal Register notice seeking comment on two applicability provisions. On February 2-3, 1999, EPA convened a public meeting to listen to new stakeholder proposals for streamlining NSR applicability and control technology requirements. Stakeholder groups submitted written proposals during May and June 1999. Discussions on these proposals will conclude by October 1999.

Anticipated Cost and Benefits:

From a cost perspective, the proposed rulemaking represents a decrease in applications and recordkeeping costs to industry of at least $13 million per year, as compared to the preexisting program, based primarily on the fact that fewer sources will need to apply for major source permits. In addition, the cost to State and local agencies will be reduced by approximately $1.4 million per year. The Federal Government should realize a savings of approximately $116,000 per year. Additional cost reductions, which are difficult to quantify, will be realized due to the streamlining effect of the rulemaking on the permitting process, for example, the opportunity costs for shorter time periods between permit application and project completion and reduced uncertainty in planning for future source growth.

Risks:

This is a procedural rule applicable to a wide variety of source categories. Moreover, it applies to criteria pollutants for which NAAQS have been established. This action is considered environmentally neutral. However, any potential risks are considered in the NAAQS rulemaking from a national perspective.

Timetable:

Action	Date	FR Cite
NPRM	07/23/96	61 FR 38249
NPRM - Utility Sector Offramp Program	11/00/00	
Final Action	12/00/00	
Final Action - Utility Sector Offramp Program	04/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 3259

See also SAN 4390

Agency Contact:

Dennis Crumpler
Environmental Protection Agency
Air and Radiation
MD-12
Research Triangle Park, NC 27711
Phone: 919 541-0871
Fax: 919 541-5509
Email: crumpler.dennis@epa.gov

RIN: 2060–AE11

EPA

112. OPERATING PERMITS: REVISIONS (PART 70)

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 7661 et seq

CFR Citation:

40 CFR 51; 40 CFR 52; 40 CFR 70

Legal Deadline:

None

Abstract:

In response to litigation on the operating permits rule regulations, 40 CFR part 70, to provide more effective implementation of part 70, and to address comments provided in response to notices of proposed rulemaking, parts 70, 51 and 52 are being revised. The changes streamline the procedures for revising stationary-source operating permits issued by State and local permitting authorities under title V of the Clean Air Act.

Statement of Need:

These revised rules will allow more streamlined procedures for revising operating permits. These revisions reflect the principles articulated in the President's and the Vice President's March 16, 1995 report Reinventing Environmental Regulation. That report established as goals for environmental regulation the building of partnerships between EPA and State and local agencies, minimizing costs, providing flexibility in implementing programs, tailoring solutions to the problem, and shifting responsibility to State and local programs.

Alternatives:

In response to concerns expressed in comments on the draft final rulemaking, the EPA discussed alternatives with representatives from State and local permitting authorities and industry and environmental groups, and desires public comment on some of the proposed alternatives. EPA will then consider public comments before promulgating a final rule.

Anticipated Cost and Benefits:

The administrative cost of implementing these proposed rules by permitting authorities, EPA, and permitted sources has not yet been estimated, but is expected to be lower than the cost of the current rule. Administrative costs include a range of costs which cover the source's preparing an application through EPA's and the permitting authority's effort to complete the process.

Risks:

All major sources of air pollution are required to have a permit to operate by the Clean Air Act. No adverse effect on the public health or ecosystems should result from this action, because the rule will require permit revisions with significant environmental impact to undergo public and EPA review.

Timetable:

Action	Date	FR Cite
NPRM	08/29/94	59 FR 44460
Supplemental NPRM Part 71	04/27/95	60 FR 20804
Supplemental NPRM Part 70	08/31/95	60 FR 45530
Direct Final Interim Approval Extension	07/27/98	63 FR 40054
NPRM Interim Approval Extension	07/27/98	63 FR 40053
NPRM	12/00/00	
Final Action	12/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

State, Local

Additional Information:

SAN No. 3412

Agency Contact:

Ray Vogel
Environmental Protection Agency
Air and Radiation
MD-12
Research Triangle Park, NC 27711
Phone: 919 541-3153
Fax: 919 541-5509
Email: vogel.ray@epa.gov

RIN: 2060–AF70

EPA

113. NESHAP: PLYWOOD AND COMPOSITE WOOD PRODUCTS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7412(d)

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Statutory, November 15, 2000.

Abstract:

This project is to develop national emission standards for hazardous air pollutants (NESHAP) by establishing maximum achievable control technology (MACT) for facilities manufacturing wood panels and engineered wood products. MACT standards are under development to reduce the release of hazardous air pollutants (HAP) from all industries to protect the public health and environment. Emissions of HAP from this industry have been associated with, but are not limited to, the drying of wood and binders. This rule is anticipated to apply to the manufacture of products involving wood and some kind of binder or bonding agent. This project may include, but is not limited to, facilities that manufacture waferboard, hardboard fiber board, oriented strandboard (OSB), medium density fiberboard (MDF), particleboard, strawboard, hardwood and softwood plywood, glue-laminated lumber, laminated veneer lumber, and engineered wood products. The source category may also include lumber drying kilns at sawmills which are located on the same site as a facility that manufactures any of the wood products mentioned above. The project may also include some coatings operations. The name of the source category was formerly Plywood and Particleboard MACT.

Statement of Need:

Plywood and Composite Wood Products is a source category listed to be regulated under Section 112 of the Clean Air Act

Summary of Legal Basis:

Clean Air Act Section 112

Alternatives:

The principal alternatives are to set standards at or beyond the ''floor'' level of stringency. The ''floor'' is the

minimum stringency implied by the congressionally given formula in section 112 of the Clean Air Act.

Anticipated Cost and Benefits:

It is expected that this rule will result in significant costs to the affected industry, including costs for recordkeeping and reporting. These costs will be identified as the proposal is developed.

Risks:

In Section 112 of the Clean Air Act, Congress found that there is sufficient evidence of risk to warrant a broad, technology-based MACT program to reduce toxic emissions nationwide. Therefore, separate risk analyses are not conducted for individual rulemakings within the MACT program.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	
Final Action	12/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local

Additional Information:

SAN No. 3820

Sectors Affected:

32121 Veneer, Plywood, and Engineered Wood Product Manufacturing

Agency Contact:

Mary Tom Kissell
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-4516
Fax: 919 541-0246
Email: kissell.mary@epa.gov

Kent C. Hustvedt
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-5395
Fax: 919 541-0246
Email: hustvedt.ken@epa.gov

RIN: 2060–AG52

EPA

114. NESHAP: RECIPROCATING INTERNAL COMBUSTION ENGINE

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 7412 CAA sec 112; PL 101-549

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Statutory, November 15, 2000.

Abstract:

The stationary reciprocating internal combustion engine source category is listed as a major source of hazardous air pollutants (HAPs) under section 112 of the Clean Air Act (CAA). A major source is one which emits more than 10 tons/yr of one HAP or more than 25 tons/yr of a combination of 189 HAPs. The EPA will gather information on HAP emissions from internal combustion engines and determine the appropriate maximum achievable control technology (MACT) to reduce HAP emissions, if any. The EPA will also gather information for NOx, SO2, CO, and PM and decide whether standards are required to reduce these emissions. The EPA will use information that has already been developed, if possible, by gathering information by working with State/local agencies, vendors, manufacturers of internal combustion engines, owners and operators of internal combustion engines, and environmentalists.

Statement of Need:

Reciprocating Internal Combustion Engines is a source category listed to be regulated under section 112 of the Clean Air Act.

Summary of Legal Basis:

Section 112 of the Clean Air Act

Alternatives:

The principal alternatives are to set standards at or beyond the ''floor'' level of stringency. The ''floor'' is the minimum stringency implied by the congressionally given formula in section 112 of the Clean Air Act.

Anticipated Cost and Benefits:

It is expected that this rule will result in significant costs to the affected industry, including costs for recordkeeping and reporting. These costs will be identified as the proposal is developed.

Risks:

In Section 112 of the Clean Air Act, Congress found that there is sufficient evidence of risk to warrant a broad, technology-based MACT program to reduce toxic emissions nationwide. Therefore, separate risk analyses are not conducted for individual rulemakings within the MACT program.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	
Final Action	11/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

None

Additional Information:

SAN No. 3656

Agency Contact:

Sims Roy
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-5263
Fax: 919 541-5450
Email: roy.sims@epa.gov

Robert J. Wayland
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-1045
Fax: 919 541-5450
Email: wayland.robertj@epa.gov

RIN: 2060–AG63

EPA

115. NESHAP: COMBUSTION TURBINE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 7412 CAA sec 112

CFR Citation:

44 CFR 63

Legal Deadline:

Final, Statutory, November 15, 2000.

Abstract:

The combustion turbine source category is listed as a major source of hazardous air pollutants (HAPs) under section 112 of the Clean Air Act (CAA). A major source is one which emits more than 10 tons/yr of one HAP or more than 25 tons/yr of a combination of 189 HAPs. Combustion turbines also emit NOx, SO2, CO, and PM. Combustion turbines are already regulated for NOx and SO2 emissions under section 111 of the CAA. The EPA will gather information on HAP emissions from combustion turbines and determine the appropriate maximum achievable control technology (MACT) to reduce HAP emissions, if any. The EPA will also gather information to revise the 1979 NSPS for NOx and SO2 and decide whether CO and PM standards are required for combustion turbines. The EPA information that has already been developed will be used if possible and additional information will be gathered by working with State/local agencies, vendors, manufacturers of combustion turbines, owners and operators of combustion turbines, and environmentalists.

Statement of Need:

Combustion Turbines is a source category listed to be regulated under Section 112 of the Clean Air Act.

Summary of Legal Basis:

Section 112 of the Clean Air Act

Alternatives:

The principal alternatives are to set standards at or beyond the ''floor'' level of stringency. The ''floor'' is the minimum stringency implied by the congressionally-given formula in section 112 of the Clean Air Act.

Anticipated Cost and Benefits:

It is expected that this rule will result in significant costs to the affected industry, including costs for recordkeeping and reporting. These costs will be identified as the proposal is developed.

Risks:

In Section 112 of the Clean Air Act, Congress found that there is sufficient evidence of risk to warrant a broad, technology-based MACT program to reduce toxic emissions nationwide. Therefore, separate risk analyses are not conducted for individual rulemakings within the MACT program.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	
Final Action	09/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Local

Additional Information:

SAN No. 3657

Agency Contact:

Sims Roy
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-5263
Fax: 919 541-5450
Email: roy.sims@epa.gov

Robert J. Wayland
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-1045
Fax: 919 541-5450
Email: wayland.robertj@epa.gov

RIN: 2060–AG67

EPA

116. NESHAP: INDUSTRIAL, COMMERCIAL AND INSTITUTIONAL BOILERS AND PROCESS HEATERS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 7412

CFR Citation:

40 CFR 63

Legal Deadline:

Final, Statutory, November 15, 2000.

Abstract:

The Clean Air Act, as amended in 1990, requires EPA to develop emission standards for sources of hazardous air pollutants (HAPs). Industrial boilers, institutional/commercial boilers and process heaters are among the potential source categories to be regulated under section 112 of the CAA. Emissions of HAPs will be addressed by this rulemaking for both new and existing sources. EPA promulgated an NSPS for these source categories in 1987 and 1990. The standards for the NESHAP are to be technology-based and are to require the maximum achievable control technology (MACT) as described in section 112 of the CAA.

Statement of Need:

Industrial boilers, institutional/commercial boilers, and process heaters are source categories listed to be regulated under section 112 of the Clean Air Act.

Summary of Legal Basis:

Section 112 of the Clean Air Act

Alternatives:

Alternatives will be explored as the proposal is developed. At this early stage, no alternatives have yet been identified.

Anticipated Cost and Benefits:

It is expected that this rule will result in significant costs to the affected industry, including costs for recordkeeping and reporting. These costs will be identified as the proposal is developed.

Risks:

The risks from this industry are expected to be those normally associated with combustion, such as exposure to particulate matter and sulfur oxides. These will be addressed as the proposal is developed.

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	
Final Action	02/00/02	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local

Federalism:

Undetermined

Additional Information:

SAN No. 3837

Agency Contact:

James Eddinger
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-5426
Fax: 919 541-5450
Email: eddinger.jim@epa.gov

William Maxwell
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-5430
Fax: 919 541-5450
Email: maxwell.bill@epa.gov

RIN: 2060–AG69

EPA

117. REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER

Priority:

Economically Significant

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 7408; 42 USC 7409

CFR Citation:

40 CFR 50

Legal Deadline:

Final, Statutory, July 18, 2000, Completion of review.

Abstract:

On July 18, 1997, the EPA published a final rule revising the national ambient air quality standards (NAAQS) for particulate matter (PM) (62 FR 38652). While retaining the PM10 standard levels, new standards were added for fine particles (PM2.5) to provide increased protection against both health and environmental effects of PM. On the same day, a Presidential Memorandum (62 FR 38421, July 16, 1997) was published that, among other things, directed EPA to complete the next review of the PM NAAQS by July 2002. The EPA's plans and schedule for the next periodic review of the PM NAAQS were published on October 23, 1997 (62 FR 55201). As with other NAAQS reviews, a rigorous assessment of relevant scientific information will be presented in a Criteria Document (CD), and the preparation of this document is currently under way by the EPA's National Center for Environmental Assessment. The EPA's Office of Air Quality Planning and Standards will also prepare a Staff Paper (SP) for the Administrator which will evaluate the policy implications of the key studies and scientific information contained in the CD and additional technical analyses and identify critical elements that EPA staff believe should be considered in reviewing the standards. The SP and CD will be reviewed by the Clean Air Scientific Advisory Committee (CASAC) and the public; both will reflect the input received through these reviews. As the PM NAAQS review is completed, the Administrator's proposal to revise or reaffirm the PM NAAQS will be published with a request for public comment. Input received during the public comment period will be reflected in the Administrator's final decision which will be published in July 2002.

Statement of Need:

As established in the Clean Air Act, the national ambient air quality standards for particulate matter are to be reviewed every five years.

Summary of Legal Basis:

Section 109 of the Clean Air Act (42 USC 7409) directs the Administrator to propose and promulgate ''primary'' and ''secondary'' national ambient air quality standards for pollutants identified under section 108 (the ''criteria'' pollutants). The ''primary'' standards are established for the protection of public health, while ''secondary'' standards are to protect against public welfare or ecosystem effects.

Alternatives:

The main alternatives for the Administrator's decision on the review of the national ambient air quality standards for particulate matter are whether to reaffirm or revise the existing standards.

Anticipated Cost and Benefits:

Costs and benefits of revising or reaffirming the national ambient air quality standards for particulate matter cannot be determined at present; a regulatory impact analysis will be conducted along with the review of the standards.

Risks:

The current national ambient air quality standards for particulate matter are intended to protect against public health risks associated with morbidity or premature mortality from cardiopulmonary disease. During the course of this next review, a risk assessment will be conducted to evaluate health risks associated with retention or revision of the particulate matter standards.

Timetable:

Action	Date	FR Cite
NPRM	08/00/01	
Final Action	07/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4255

Agency Contact:

Mary A. Ross
Environmental Protection Agency
Air and Radiation
MD-15
Research Triangle Park, NC 27711
Phone: 919 541-5170
Fax: 919 541-0237
Email: ross.mary@epamail.epa.gov

Karen Martin
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-5274
Fax: 919 541-0877
Email: martin.karen@epamail.epa.gov

RIN: 2060–AI44

EPA

118. TRANSPORTATION CONFORMITY AMENDMENTS: RESPONSE TO MARCH 2, 1999, COURT DECISION

Priority:

Other Significant

Legal Authority:

42 USC 7401-7671q

CFR Citation:

40 CFR 93

Legal Deadline:

None

Abstract:

The Clean Air Act requires EPA to promulgate rules that establish the criteria and procedures for determining whether highway and transit plans,

programs, and projects conform to State air quality plans. ''Conformity'' means that the transportation actions will not cause or worsen violations of air quality standards or delay timely attainment of the standards. The original conformity rule was finalized on November 24, 1993, and most recently amended on August 15, 1997. On March 2, 1999, the U.S. Court of Appeals overturned certain provisions of the 1997 conformity amendments. This rulemaking will amend the conformity rule in compliance with the court decision. The rulemaking will formalize the May 14, 1999 EPA guidance and the June 18, 1999 DOT guidance that was issued to guide action on this issue until a rulemaking could be issued. Specifically, the rulemaking will clarify the types of projects that can be implemented in the absence of a conforming transportation plan. It will also explain EPA's process for reviewing newly submitted air quality plans and when those submissions can be used for conformity purposes.

Statement of Need:

The U.S. Court of Appeals remanded some provisions of EPA's conformity rule. The conformity rule must be amended in compliance with the court decision.

Summary of Legal Basis:

The Clean Air Act requires transportation plans, programs, and projects to conform to state air quality plans. The Clean Air Act also requires EPA to establish rules for how to determine the conformity of transportation actions.

Alternatives:

EPA's alternatives are constrained by the court decision.

Anticipated Cost and Benefits:

This amendment will not change the results of the economic analysis performed for the original transportation conformity rule, which was summarized in the preamble to that rule on 11/24/93 at 58 FR 62214.

Risks:

Transportation conformity is a process designed to help achieve attainment with the National Ambient Air Quality Standards. The risks addressed by the rule are therefore those risks associated with non-achievment of such standards.

Timetable:

Action	Date	FR Cite
NPRM	03/00/01	
Final Rule	12/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4340

Agency Contact:

Kathryn Sargeant
Environmental Protection Agency
Air and Radiation
RSPD
Washington, DC 20460
Phone: 734 214-4441
Fax: 734 214-4052
Email: sargeant.kathryn@epa.gov

RIN: 2060–AI56

EPA

119. • RULEMAKINGS FOR THE PURPOSE OF REDUCING INTERSTATE OZONE TRANSPORT

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

Not Yet Determined

CFR Citation:

40 CFR 51

Legal Deadline:

None

Abstract:

The Clean Air Act (CAA) requires that a State implementation plan (SIP) contain provisions to prevent a State's facilities or sources from contributing significantly to air pollution that is ''transported'' downwind to other States, exacerbating their inability to meet the national ambient air quality standards for ozone. Through a 2-year effort known as the Ozone Transport Assessment Group (OTAG), EPA worked in partnership with the 37 easternmost States and the District of Columbia, industry representatives, and environmental groups to address ozone transport. This multiyear collaboration resulted in the most comprehensive analysis of ozone transport ever conducted. The OTAG States voted in favor of a range of strategies to reduce nitrogen oxide emissions from utilities and other major sources. Building on the recommendations of OTAG, EPA issued a rule known as the NOx SIP Call (10/27/98, 63 FR 57355) requiring 22 States and the District of Columbia to submit revisions to their SIPs to address the regional transport of nitrogen oxides (a precursor to ozone formation known as NOx). By reducing emissions of NOx, the actions directed by these plans will decrease the formation and transport of ozone across State boundaries in the eastern half of the United States. The U.S. Court of Appeals upheld most provisions of the rule earlier this year. The court did remand certain minor provisions which EPA is now addressing in a separate rulemaking — see SAN 4433 in today's regulatory agenda.) In addition to the SIP Call provisions, Federal Implementation Plans (FIPs) may also be needed to reduce regional transport if any affected State fails to adequately revise its SIP to comply with the NOx SIP call (see SAN 4096 in today's regulatory agenda). In addition to the SIP Call remedy, the Clean Air Act also gave States the right to petition EPA to take other Federal action to prevent ozone transport that affects downwind States. Accordingly, under section 126 of the CAA, eight northeastern States filed petitions requesting EPA to make findings and require decreases in NOx emissions from certain stationary sources in upwind States that may significantly contribute to ozone nonattainment problems in the petitioning State. After analysis, EPA found the petitions from eight States to be meritorious in whole or in part (5/25/99, 64 FR 28250). Subsequently, EPA issued a final rule on the petitions, specifying a NOx emissions trading program as the required Federal remedy (1/18/00, 65 FR 2764). EPA is coordinating all three approaches to regional ozone control — i.e., SIP Call, FIPs, and section 126 actions — to avoid duplication and maximize effectiveness.

Statement of Need:

It has long been recognized that ozone transport is a major factor in the difficulty many States are having in attaining the clean-air standards for ozone. This was made more clear by the OTAG analysis outlined above.

Summary of Legal Basis:

Clean Air Act Sections 110 and 126

Alternatives:

The Clean Air Act specifies the SIP Call process, the FIP process, and the section 126 petition process as alternate approaches to remedying the problem of ozone transport. EPA intends to use these alternatives as appropriate in an integrated program.

Anticipated Cost and Benefits:

As outlined in the Regulatory Impact Analysis for the NOx SIP Call, the rule will result in significant improvements in premature mortality, chronic asthma, chronic and acute bronchitis, upper and lower respiratory symptoms, work days lost, decreased worker productivity, visibility in urban and suburban areas, increases in yields of commercial forests currently exposed to elevated ozone levels, and reductions in loadings of nitrogen to sensitivity estuaries, helping State and local government reach target reduction goals for estuaries such as Chesapeake Bay, Albermarle-Pamlico Sound and Long Island Sound. Due to practical analytical limitations, we cannot quantify and/or monetize all potential benefits of this action. Within these limitations, the quantified and monetized benefits were estimated in the Regulatory Impact Analysis to range from $1.1 billion to $4.2 billion annually. Annual costs were estimated at $1.7 billion. All figures are in 1990 dollars.

Risks:

The risks addressed by this action are the likelihood of experiencing increased health and environmental effects associated with nonattainment of the National Ambient Air Quality Standard for ozone. These effects are briefly described above in the ''costs and benefits'' section, and they are outlined in detail in the Regulatory Impact Analysis for the NOx SIP Call.

Timetable:

Action	Date	FR Cite
NPRM - NOx FIPs (SAN 4096)	10/21/98	63 FR 56393
Final Action - NOx SIP Call	10/27/98	63 FR 57355
Final Action - Section 126 Findings	05/25/99	64 FR 28250
Final Action - Section 126 Approvals and Remedy	01/18/00	65 FR 2674
NPRM - Response to NOx SIP Call Court Decision (SAN 4433)	10/00/00	
Final Action - Response to NOx SIP Call Court Decision (SAN 4433)	12/00/00	
Final Action - NOx FIPs (SAN 4096)	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

Additional Information:

SAN No. 4466

Agency Contact:

Carla Oldham
Environmental Protection Agency
Air and Radiation
MD-15
Research Triangle Park, NC 27711
Phone: 919 541-3347
Fax: 919 541-0824
Email: oldham.carla@epa.gov

Kimber Scavo
Environmental Protection Agency
Air and Radiation
MD-15
Research Triangle Park, NC 27711
Phone: 919 541-3354
Fax: 919 541-0824
Email: scavo.kimber@epamail.epa.gov

RIN: 2060–AJ20

EPA

120. LEAD-BASED PAINT ACTIVITIES; TRAINING AND CERTIFICATION FOR RENOVATION AND REMODELING SECTION 402(C)(3)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

15 USC 2603 TSCA Title IV; PL 102-550 Sec 402(c)(3)

CFR Citation:

40 CFR 745

Legal Deadline:

Final, Statutory, October 28, 1996.

Abstract:

Under section 402(c)(2) of the Toxic Substances Control Act (TSCA) title IV, EPA conducted a study of the extent to which persons engaged in renovation and remodeling activities in target housing are exposed to lead in the conduct of such activities or disturb lead and create a lead-based paint hazard. EPA must use the results of this study and consult with interested parties to determine which categories of renovation and remodeling activities require training and certification. EPA must then revise the training and certification regulations originally developed for individuals performing lead-based paint abatement under section 402(c)(a) of TSCA title IV to apply them to the renovation and remodeling categories. If EPA determines that any category does not require certification, EPA must publish an explanation of the basis for that determination.

Statement of Need:

Childhood lead poisoning is a pervasive problem in the United States, with almost a million young children having more than 10 ug/dl of lead in their blood, (Center for Disease Control's level of concern). Although there have been dramatic declines in blood-lead levels due to reductions of lead in paint, gasoline, and food sources, remaining paint in older houses continues to be a significant source of childhood lead poisoning. These rules will help insure that individuals and firms conducting lead-based paint activities will do so in a way that safeguards the environment and protects the health of building occupants, especially children under 6 years old.

Summary of Legal Basis:

This regulation is mandated by TSCA section 402(c). TSCA section 402(c) directs EPA to address renovation and remodeling activities by first conducting a study of the extent to which persons engaged in various typed of renovation and remodeling activities are exposed to lead in the conduct of such activities or disturb lead and create a lead-based paint hazard on a regular basis. Section 402(c) further directs the Agency to revise the lead-based paint activities regulations (40 CFR part 745 subpart L) to include renovation or remodeling activities that create lead-based paint hazards. In order to determine which contractors are engaged in such activities the Agency is directed to utilize the results of the study and consult with the representatives of labor organizations, lead-based paint activities contractors, persons engaged

in remodeling and renovation, experts in health effects, and others.

Alternatives:

TSCA section 402(c) states that should the Administrator determine that any category of contractors engaged in renovation or remodeling does not require certification; the Administrator may publish an explanation of the basis for that determination.

Anticipated Cost and Benefits:

EPA's quantitative cost estimates fall into four categories: Training Costs, Work Practice Costs, Clearance Testing Costs, and Administrative Costs. The estimates vary depending upon the option selected. In most cases we expect that requirements related to Clearance Testing and Work Practices will contribute the most to overall rule cost. The benefits analysis will not provide direct quantitative measures of each (or any) option. EPA does not have a complete risk assessment (with dose-response functions) that would permit direct quantitative estimates. We do have other data, such as estimated loadings of lead generated by renovation work, number and type of renovation events, demographics of the exposed population, and the costs of various health effects previously linked to lead exposure. With the available information we are able utilize several qualitative approaches to frame the benefits associated with an effective renovation rule.

Risks:

These rules are aimed at reducing the prevalence and severity of lead poisoning, particularly in children. The Agency has concluded that many R&R work activities can produce or release large quantities of lead and may be associated with elevated blood lead levels. These activities include, but are not limited to: sanding, cutting, window replacement, and demolition. Lead exposure to R&R workers appears to be less of a problem than to building occupants (especially young children). Some workers (and homeowners) are occasionally exposed to high levels of lead. Any work activity that produces dust and debris may create a lead exposure problem.

Timetable:

Action	Date	FR Cite
NPRM	08/00/01	
Final Action	02/00/03	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 3557

Sectors Affected:

23321 Single Family Housing Construction; 23322 Multifamily Housing Construction; 23521 Painting and Wall Covering Contractors; 23551 Carpentry Contractors; 23599 All Other Special Trade Contractors; 53111 Lessors of Residential Buildings and Dwellings; 531311 Residential Property Managers; 54138 Testing Laboratories

Agency Contact:

Lin Moos
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7404
Washington, DC 20460
Phone: 202 260-1866
Fax: 202 260-0770
Email: moos.lin@epa.gov

Mike Wilson
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7404
Washington, DC 20460
Phone: 202 260-4664
Fax: 202 260-0770
Email: wilson.mike@epa.gov

RIN: 2070–AC83

EPA

121. ENDOCRINE DISRUPTOR SCREENING PROGRAM

Priority:

Other Significant

Legal Authority:

15 USC 2603 TSCA; 21 USC 346(a) FFDCA; 42 USC 300(a)(17) SDWA; 7 USC 136 FIFRA

CFR Citation:

Not Yet Determined

Legal Deadline:

NPRM, Statutory, August 3, 1998, EDSP must be Developed.

Final, Statutory, August 3, 1999, Agency must Implement.

Other, Statutory, August 3, 2000, Agency must report to Congress on EDSP.

Abstract:

This final policy statement will set forth EPA's Endocrine Disruptor Screening Program. EPA published a proposed policy statement setting forth the Screening Program on December 28, 1998. In the final policy statement, EPA will describe the screens and tests that it will require as part of the program. It also will describe the universe of chemicals that will be included in the program, the priority-setting mechanism that used to determine the order in which those chemicals will be tested, and certain issues related to implementing the program. The major actions in 2000 and 2001 will be the standardization and validation of assays in the screening battery and the completion of the priority-setting system.

Statement of Need:

The Endocrine Disruptor Screening Program fulfills the statutory direction and authority to screen pesticide chemicals and drinking water contaminants for their potential to disrupt the endocrine system and adversely affect human health.

Summary of Legal Basis:

The mandate to screen pesticide chemicals for estrogenic effects that may affect human health is the Federal Food, Drug and Cosmetic Act (FFDCA) as amended in the Food Quality Protection Act (21 U.S.C. 346a(p)). FFDCA also provides EPA authority to require testing of substances that may have an effect that is cumulative to that of a pesticide chemical. Discretionary authority to test contaminants in sources of drinking water is in the Safe Drinking Water Act as amended in 1996 (42 U.S.C. 300j-17). General authority to test chemicals and pesticides is in TSCA (15 U.S.C. 2603) and FIFRA (7 U.S.C. 136) respectively.

Alternatives:

A Federal role is mandated under cited authority. There is no alternative to the role of the Federal Government on this issue to ensure that pesticides, commercial chemicals and contaminants are screened and tested for endocrine disruption potential. A limited amount of testing may be conducted voluntarily, but this will fall far short of the systematic screening which is necessary to protect public health and the environment and ensure the public that all important substances have been adequately evaluated.

Anticipated Cost and Benefits:

It is too early to project the costs and benefits of this program accurately. However, as a rough estimate, the screening battery is estimated to cost $200,000 per chemical. It is also too early to quantify the benefits of this program mathmetically. The goal of the program is to reduce the risks identified below.

Risks:

Evidence is continuing to mount that wildlife and humans may be at risk from exposure to chemicals operating through an endocrine mediated pathway. Preliminary studies show decreases on IQ tests and increases in aggression in children. Severe malformations of the genitals of boys have increased steadily over the last two decades. Wildlife effects have been more thoroughly documented. Abnormalities in birds, marine mammals, fish and shellfish have been documented in the United States, Europe, Japan, Canada, and Australia which have been linked to specific chemical exposures. Evidence is sufficient for the United States to proceed on a two-track strategy: research on the basic science regarding endocrine disruption and screening to identify which chemicals are capable of interacting with the endocrine system. The combination of research and test data developed by this program will enable EPA to take action to reduce chemical risks.

Timetable:

Action	Date	FR Cite
Notice - Outline of Screening Program	08/11/98	63 FR 42852
Notice - Proposed Screening Program & Request for Comment	12/28/98	63 FR 71542
NPRM - Proposed Procedural Rule	12/00/01	
Final Action - Final Screening Program	12/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Additional Information:

SAN No. 4143

In August 2000, the Agency submited the required Status Report to Congress.

Agency Contact:

Gary Timm
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7201
Washington, DC 20460
Phone: 202 260-3573
Fax: 202 401-1282
Email: timm.gary@epa.gov

Anthony Maciorowski
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7201
Washington, DC 20460
Phone: 202 260-3573
Fax: 202 401-1282
Email: maciorowski.anthony@epa.gov

RIN: 2070–AD26

EPA

122. HAZARDOUS WASTE MANIFEST REGULATION

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 6922 RCRA sec 3002; 42 USC 6923 RCRA sec 3003; 42 USC 6926 RCRA sec 3006

CFR Citation:

40 CFR 260; 40 CFR 262; 40 CFR 263; 40 CFR 264; 40 CFR 265; 40 CFR 271

Legal Deadline:

None

Abstract:

The Uniform Hazardous Waste Manifest (Form 8700-22) is a multicopy form used to identify the quantity, composition, origin, routing, and destination of hazardous waste during its transportation. The manifest system's reliance on paper results in significant paperwork and cost burden to waste handlers and States who choose to collect manifest information. The Agency is considering an optional approach to redesign the manifest system so that it utilizes automated technologies to increase access to manifest-related information, and to facilitate the manifest process, including the form's preparation, transmission, and recordkeeping, thereby lessening the total burden on waste handlers and States that choose to collect manifests. In addition, the Agency is considering further standardizing further the manifest form itself by eliminating several optional data fields and by specifying one format that may be used in all States.

Statement of Need:

The Agency is considering revising the RCRA manifest system because of the amount of paperwork burden associated with the manifest. Reduction in paperwork burden is part of the Administration's Regulatory Reinvention goal of cutting government red tape. The Agency wants to further standardize the manifest program across States by introducing a more uniform manifest tracking form. The chief goal of the manifest system is to facilitate the safe transportation of offsite shipments of hazardous waste to appropriate RCRA management facilities. Furthermore, the manifest promotes accountability throughout the generation, transportation, and disposal cycle of a hazardous waste shipment; and the manifest also provides essential hazard information to handlers and emergency responders.

Summary of Legal Basis:

RCRA section 3002(a)(5) authorizes EPA to issue regulations applicable to generators of hazardous waste regarding the use of a manifest system to describe waste, its origin, and its routing to ensure waste arrives at designated off-site facilities. RCRA sections 3003 and 3004 authorize EPA to issue regulations applicable to transportors of hazardous waste and to treatment, storage, and disposal facilities regarding compliance with the manifest system.

Alternatives:

The Agency has looked at two alternatives to revising the manifest system. The first alternative is to revise and standardize the manifest form itself. The second alternative is to introduce the option of automated technologies (electronic commerce) to reduce paperwork and make the manifest system more efficient. The Agency is considering combining these alternatives in a proposed rule.

Anticipated Cost and Benefits:

EPA is considering actions that should impose minimal costs on the regulated industry, since the Agency is evaluating a reduction in the overall number of elements on the manifest form. Additionally, greater uniformity in data

required across the United States would benefit waste handlers by reducing the burden associated with obtaining multiple manifests from different States, as well as being aware of various uses of optional fields. Other hazardous waste handlers would benefit from having the option to use automation to complete, send, receive, and store manifest information. Some States may have to modify their data systems in response to changes in the manifest form. The Agency is currently conducting an analysis to determine the costs and benefits of revisions to the manifest system.

Risks:

This proposed rule is intended to reduce the paperwork burden of the manifest on the public without reducing protectiveness of human health or the environment.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 3147

Sectors Affected:

2111 Oil and Gas Extraction; 2122 Metal Ore Mining; 2211 Electric Power Generation, Transmission and Distribution; 3221 Pulp, Paper, and Paperboard Mills; 323 Printing and Related Support Activities; 325 Chemical Manufacturing; 326 Plastics and Rubber Products Manufacturing; 331 Primary Metal Manufacturing; 332 Fabricated Metal Product Manufacturing; 482 Rail Transportation; 483 Water Transportation; 484 Truck Transportation; 5621 Waste Collection; 5622 Waste Treatment and Disposal

Agency Contact:

Rich Lashier
Environmental Protection Agency
Solid Waste and Emergency Response
5304W
Washington, DC 20460
Phone: 703 308-8796
Fax: 703 308-0522
Email: lashier.rich@epamail.epa.gov

RIN: 2050–AE21

EPA

123. STANDARDIZED PERMIT FOR RCRA HAZARDOUS WASTE MANAGEMENT FACILITIES

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 6905; 42 USC 6912; 42 USC 6924; 42 USC 6925; 42 USC 6927; 42 USC 6939; 42 USC 6974

CFR Citation:

40 CFR 124; 40 CFR 267; 40 CFR 270

Legal Deadline:

None

Abstract:

EPA is considering allowing a type of general permit, called a standardized permit, for facilities that generate waste and routinely manage the waste on-site in tanks, containers, and containment buildings. Under the standardized permit, facility owners and operators would certify compliance with generic design and operating conditions set on a national basis. The permitting agency would review the certifications submitted by the facility owners or operators. The permitting agency would also be able to impose additional site-specific terms and conditions for corrective action or other purposes, as called for by RCRA. Ensuring compliance with the standardized permit's terms and conditions would occur during inspection of the facility after the permit has been issued.

Statement of Need:

The Agency convened a special task force in 1994 to look at permitting activities throughout its different programs and to make specific recommendations to improve these permitting programs. This task force, known as the Permits Improvement Team (PIT), spent two years working with stakeholders from the Agency, State-permitting agencies, industry, and the environmental community. The PIT stakeholders mentioned, among other things, that permitting activities should be commensurate with the complexity of the activity. The stakeholders felt that current Agency permitting programs were not flexible enough to allow streamlined procedures for routine permitting activities.

Currently, facilities that store, treat, or dispose of hazardous waste must obtain site-specific ''individual'' permits prescribing conditions for each ''unit'' (e.g., tank, container area, etc.) in which hazardous waste is managed. Experience gained by the Agency and States over the past 16 years has shown that not all waste management activities are at the same level of complexity. Some activities, such as thermal treatment or land disposal of hazardous waste, are more complex than storage of hazardous waste. The Agency believes that thermal treatment and land disposal activities continue to warrant ''individual'' permits, prescribing unit-specific conditions. However, the Agency believes that some accommodation can be made for hazardous waste management practices in standardized units such as tanks, container storage areas, and containment buildings. The Agency's Permit Improvement Team tentatively recommended, among other things, that regulations be developed to allow ''standardized permits'' for on-site storage and nonthermal treatment of hazardous waste in tanks, containers, and containment buildings. The Agency is considering revising the RCRA regulations to allow this type of permit.

Summary of Legal Basis:

Facilities that manage hazardous waste are required under RCRA to obtain a permit and carry out corrective action as necessary (see RCRA sections 3004, 3005, 3008 and 3010). EPA has discretion under these statutory provisions to apply different permitting procedures to different types of facilities, as EPA is proposing to do here. No aspect of this streamlining action is required by court order.

Alternatives:

EPA has considered several significant alternatives or options regarding RCRA permits and corrective action issues. The Agency intends to limit the scope of the proposed rule to facilities that generate waste and manage it on-site. The Agency considered, however, and plans to ask for comment on, whether coverage of the rule should be expanded to facilities that generate waste at operations in more than one location and want to manage the waste at one location. The Agency also plans to ask for comment on the option of allowing a facility's RCRA corrective action activities to be postponed if corrective action is being carried out

under an approved State remedial program.

Anticipated Cost and Benefits:

The following cost/benefit information is based on preliminary estimates and is being provided for informational purposes only; it is subject to change. The RCRA standardized permit proposal is an optional rule designed to streamline the regulatory burden to EPA/States as well as to private sector facilities covered by the rule, by reducing the amount of information collected, submitted and reviewed for permit actions (i.e., new permit applications, permit modifications, and permit renewals). Because the rule proposes to streamline existing RCRA regulation, rather than add new RCRA regulation, implementation of the rule by the EPA and by States with EPA-authorized permitting programs is expected to result in economic benefits in the form of national cost savings from reducing both government and private sector resources required for the RCRA permit process. Based on a preliminary economic analysis, the EPA estimates that the potential average annual cost savings to eligible facilities resulting from implementation of this rule, will range from approximately $100 to $5,800 per permit action, depending on such things as the type of permit and the type of storage equipment. EPA estimates potential national cost savings of $360,000 to $530,000 per year based upon an assumed average rate of about 120 eligible permit actions per year.

Risks:

A description of risks is not applicable to the rule. The purpose of this rule is to streamline existing RCRA permit application and issuance procedures. Since facilities covered by this proposed rule are currently already required to obtain RCRA permits, this proposed rule will have minimal effects on incremental risks.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Federalism:

Undetermined

Additional Information:

SAN No. 4028

Sectors Affected:

32411 Petroleum Refineries; 3251 Basic Chemical Manufacturing; 3252 Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing; 325211 Plastics Material and Resin Manufacturing; 32532 Pesticide and Other Agricultural Chemical Manufacturing; 32551 Paint and Coating Manufacturing; 332813 Electroplating, Plating, Polishing, Anodizing and Coloring

Agency Contact:

Vernon Myers
Environmental Protection Agency
Solid Waste and Emergency Response
5303W
Washington, DC 20460
Phone: 703 308-8660
Fax: 703 308-8609
Email: myers.vernon@epa.gov

RIN: 2050–AE44

EPA

124. ● STANDARDS FOR THE MANAGEMENT OF COAL COMBUSTION WASTES GENERATED BY ELECTRIC POWER PRODUCERS

Priority:

Economically Significant

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 6907(a)(3); 42 USC 6944(a)

CFR Citation:

40 CFR 257

Legal Deadline:

None

Abstract:

This action is for the development of proposed and final RCRA subtitle D regulations for the management of coal combustion wastes in landfills and surface impoundments that are generated by producers of electric power, including electric utilities and independent power producers.

On April 25, 2000, EPA issued a regulatory determination for fossil fuel combustion wastes (65 FR 32214, May 22, 2000). The purpose of the determination was to decide whether certain wastes from the combustion of fossil fuels (including coal, oil and natural gas) should remain exempt from subtitle C (management as hazardous waste) of the Resource Conservation and Recovery Act (RCRA) for the coal, oil and natural gas combustion wastes that were addressed. The Agency's decision was to retain the exemption from hazardous waste management for all of the fossil fuel combustion wastes. However, the Agency also determined and announced that waste management regulations under RCRA subtitle D (management as nonhazardous wastes) are appropriate for certain coal combustion wastes that are disposed of in landfills and surface impoundments. We also announced that we would consult with the Department of the Interior on appropriate measures under the Surface Mining Control and Reclamation Act (SMCRA) or RCRA or some combination of both to address the disposal of coal combustion wastes when used for minefill in surface and underground mines.

The utility industry has made significant improvements in its waste management practices over recent years, and most State regulatory programs are similarly improving. Nevertheless, public comments and other analyses have convinced the Agency that coal combustion wastes could pose risks to human health and the environment if they are not properly managed. There is sufficient evidence that adequate controls may not be in place. For example, while most States can now require newer waste management units to include liners and groundwater monitoring, 62 percent of existing utility surface impoundments do not have groundwater monitoring. In the Agency's view, this justifies the development of national regulations. EPA acknowledges that some waste management units may not warrant liners and/or groundwater monitoring, depending on site-specific characteristics. The Agency is initiating this action to develop and issue appropriate waste management regulations under subtitle D of RCRA.

Statement of Need:

EPA's regulatory determination for fossil fuel combustion wastes (65 FR 32214, May 22, 2000) concluded that these wastes do not require management as hazardous wastes. However, EPA determined that certain of the coal combustion wastes have been managed improperly as indicated by identified damage cases. Although all of the proven damage cases involved past waste management practices and were appropriately addressed by either State or Federal authorities, we are

concerned about the potential risks posed via the groundwater pathway from improper management of the wastes, and lack of groundwater monitoring at more than half of the active coal combustion waste management units. While most States can now require newer waste management units to include liners and groundwater monitoring, 62 percent of existing utility surface impoundments, for example, do not have groundwater monitoring. Although not all sites may warrant the same measures, the Agency believes that the lack of groundwater monitoring and liners justifies the development of national regulations. Therefore, the Agency is initiating this action to develop and issue appropriate management regulations under subtitle D of RCRA for these wastes.

Summary of Legal Basis:

This action is not required by statute or court order.

Alternatives:

The Agency considered the need for more stringent hazardous waste management requirement for these wastes, but rejected the option. Rather, the Agency believes that any management and performance standards issued under nonhazardous waste authorities (RCRA subtitle D) would adequately protect human health and the environment.

Anticipated Cost and Benefits:

EPA has not yet developed a regulatory approach to address coal combustion wastes. Therefore, costs and benefits of potential management and performance standards have not been quantified. The costs of any regulation could be high, given the large amount of coal combustion wastes generated per year. However, those costs could be mitigated by ongoing trends in industry management and State oversight of these wastes. As EPA develops national regulations, the Agency will try to minimize disruptions to operation of existing waste management units.

Risks:

For EPA's regulatory determination for fossil fuel combustion wastes, we did not rely on a quantitative groundwater risk assessment to assess potential risks to human health or the environment. We are unable at this time to draw quantitative conclusions regarding the risks due to arsenic or other contaminants posed by improper waste management. EPA is currently reviewing its groundwater model and plans to reevaluate groundwater risks after any necessary changes to the model are completed. Based on a screening analysis that compared drinking water standards to leach test data from coal combustion waste samples, the Agency identified a potential for risks from arsenic that cannot be dismissed at this time. An EPA ecological risk assessment found the potential for risk to various fauna.

Timetable:

Action	Date	FR Cite
NPRM	09/00/01	
Final Action	08/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

Undetermined

Additional Information:

SAN No. 4470

Any Federal, state, local or tribal governments that own coal-burning electric power generating facilities will be subject to this rule.

Sectors Affected:

221112 Fossil Fuel Electric Power Generation

Agency Contact:

Dennis Ruddy
Environmental Protection Agency
Solid Waste and Emergency Response
5306W
Washington, DC 20460
Phone: 703 308-8430
Fax: 703 308-8686
Email: ruddy.dennis@epa.gov

RIN: 2050–AE81

EPA

125. EFFLUENT GUIDELINES AND STANDARDS FOR THE METAL PRODUCTS AND MACHINERY CATEGORY, PHASES 1 AND 2

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

33 USC 1311 CWA sec 301; 33 USC 1314 CWA sec 304; 33 USC 1316 CWA sec 306; 33 USC 1317 CWA sec 307; 33 USC 1317 CWA sec 308; 33 USC 1317 CWA sec 402; 33 USC 1361 CWA sec 501

CFR Citation:

40 CFR 438

Legal Deadline:

NPRM, Judicial, October 31, 2000.

Final, Judicial, December 31, 2002.

Abstract:

EPA is developing effluent limitations guidelines for facilities that generate wastewater while processing metal parts; metal products; and machinery, including manufacture, assembly, rebuilding, repair, and maintenance. A proposed rule in 1995 covered seven industrial groups: aircraft, aerospace, hardware, ordnance, stationary industrial equipment, mobile industrial equipment, and electronic equipment. EPA has consolidated this rulemaking with a second phase, and coverage will include additional industrial groups such as: bus and truck, household equipment, instruments, motor vehicles, office machines, precious metals and jewelry, railroads, job shops, printed circuit boards, and ships and boats. The deadlines and timetable apply to the consolidated Phase 1 and 2 rulemaking.

Statement of Need:

Only 25 percent of the facilities in this industry are currently regulated by national effluent limitations. Most of the industry has wastewater treatment that is inadequate, in terms of the best available technology. Those facilities that do have wastewater treatment designed those systems to meet effluent limits established by EPA over 20 years ago. The proposed MP&M limitations are based on technologies that achieve much lower levels of pollutants — for example, an 80 percent reduction in cyanide and chromium.

Summary of Legal Basis:

The Clean Water Act requires EPA to establish effluent limitations guidelines and standards to limit the pollutants discharged from point sources. In addition, EPA is bound by a provision in a consent decree entered in settlement of Natural Resources Defense Council et al. v. Reilly (D.D.C. No. 89-2980) to propose regulations for this industry by October 2000.

Alternatives:

The Clean Water Act directs EPA to establish a technology basis for the effluent guidelines. Limitations are based on the performance of specific technology levels, such as the best available technology economically achievable. EPA is considering a range of pollution control technologies and is also considering flow exemptions to reduce the impact on small dischargers.

Anticipated Cost and Benefits:

EPA expects effluent reduction benefits from more than 10,000 facilities. The estimated cost of the proposed rule is $1.9 billion, including operating and maintenance costs and annualized capital costs. For more than half of the facilities, the costs are less than $50,000 per facility. Higher costs are concentrated among a small segment of the industry. Estimated annual benefits range from $1.0 billion to $2.5 billion. These monetized benefits include health benefits (reduction in cancer and other illness), recreational benefits, and administrative savings from reduced pollutant loadings in biosolids.

Risks:

EPA estimates that compliance with this regulation will reduce the annual discharge of conventional pollutants by at least 115 million pounds, priority pollutants by 12 million pounds, and non-conventional metal and organic pollutants by 43 million pounds. These reductions represent significant improvements in water quality. The amounts are substantial in terms of point source controls.

Timetable:

Action	Date	FR Cite
NPRM (Phase 1)	05/30/95	60 FR 28210
NPRM (Consolidated Phase 1 and 2)	10/00/00	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local

Additional Information:

SAN No. 2806

For more information on Metal Products and Machinery on the Internet, please visit:

http://www.epa.gov/ost/guide/mpm/index.html

Sectors Affected:

332 Fabricated Metal Product Manufacturing; 333 Machinery Manufacturing; 334 Computer and Electronic Product Manufacturing; 335 Electrical Equipment, Appliance and Component Manufacturing; 336 Transportation Equipment Manufacturing; 337 Furniture and Related Product Manufacturing; 339 Miscellaneous Manufacturing

Agency Contact:

Shari Barash
Environmental Protection Agency
Water
4303
Washington, DC 20460
Phone: 202 260-7130
Fax: 202 260-7185
Email: barash.shari@epa.gov

Mike Ebner
Environmental Protection Agency
Water
4303
Washington, DC 20460
Phone: 202 260-5397
Fax: 202 260-7185
Email: ebner.michael@epa.gov

RIN: 2040–AB79

EPA

126. EFFLUENT GUIDELINES AND STANDARDS FOR FEEDLOTS POINT SOURCE CATEGORY, AND NPDES REGULATION FOR CONCENTRATED ANIMAL FEEDING OPERATIONS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

33 USC 1318 CWA sec 308; 33 USC 1342 CWA sec 402; 33 USC 1317 CWA sec 307; 33 USC 1311 CWA sec 301; 33 USC 1314 CWA sec 304; 33 USC 1316 CWA sec 306; 33 USC 1361 CWA sec 501

CFR Citation:

40 CFR 412; 40 CFR 122.23

Legal Deadline:

NPRM, Judicial, December 15, 2000.

Final, Judicial, December 15, 2002.

Abstract:

Feedlot operations are covered by existing effluent guidelines at 40 CFR 412 and concentrated animal feeding operations (CAFOs) are covered by permitting regulations at 40 CFR 122.23. This action will revise the existing effluent guidelines to address swine, poultry, beef, and dairy cattle operations and the NPDES regulation for concentrated animal feeding operations. The existing regulations, which require the largest confined animal feeding operations to achieve zero discharge of wastes to surface waters except for certain storm related discharges, have not been sufficient to resolve water quality impairment from feedlot operations. Feedlot operations are substantial contributors of nutrients in surface waters that have severe anoxia (low levels of dissolved oxygen) and problem algae blooms.

Statement of Need:

Since the existing CAFO regulations were promulgated in the 1970s, the animal production industry has changed significantly, rendering the regulations less effective in protecting water quality than is needed. Contamination of surface water results from breaches of lagoons, runoff from feedlots, direct contact of animals with surface water, and manure applied to land in excess of crop nutrient needs. Nutrients, most notably nitrogen and phosphorus, are essential for profitable crop and animal agriculture. However, nitrogen and phosphorus export in watershed runoff can accelerate the eutrophication of surface waters. Rapid growth and intensification of animal production in many areas has created regional imbalances in nutrient inputs and nutrient output. In many of these areas, nutrients produced in animal manure exceed crop needs and pose risks to the environment.

Summary of Legal Basis:

The Clean Water Act (CWA) authorizes EPA to establish and to revise, if appropriate, effluent limitations guidelines and standards to regulate the quality of point source discharges. The Act also authorizes EPA to promulgate implementing regulations for the NPDES permitting program. EPA is also required to revisit these effluent guidelines to satisfy a provision in a consent decree entered in settlement of Natural Resources Defense Council et al. v. Reilly, (D.D.C. No. 89-2980). In addition, the proposed revisions to the NPDES implementing regulations for CAFOs will satisfy an obligation in a settlement agreement associated with the same case.

Alternatives:

The CWA requires effluent guidelines to be established on a technology basis. Limitations are generally based on the performance of specific technology levels, such as the best available technology economically achievable. For animal feeding operations, EPA is considering a range of regulatory alternatives that includes management practices, traditional pollution control technologies, and alternative technologies/practices that recover the energy value or alter the handling/marketability characteristics of animal wastes. EPA is also considering whether alternative pollution control requirements should be established for smaller animal feeding operations.

The NPDES regulation for CAFOs defines which facilities are covered by the permit regulation, and will specify the permit requirements necessary to protect water quality. EPA is considering adding additional animal types to its definition, and is considering amending the size facility or conditions that define which facilities are CAFOs subject to permitting. Permit requirements that address land application of manure are also being considered.

Anticipated Cost and Benefits:

The types of benefits associated with revisions to effluent guidelines for animal feeding operations chiefly involve improvements to surface water quality. Reduced risks to human health are expected to result from these improvements. Surface water benefits will principally derive from reduced loadings of nutrients in runoff from animal confinement, manure storage, and land applications areas. Discharges of metals and pathogens to surface waters will also be reduced. This reduction in pathogens will result in fewer beach and shellfish bed closings. The costs associated with this regulation will include capital expenses to purchase or install facility upgrades to the existing manure storage structures and feedlot stormwater diversions; transportation of manure off-site; and fees for preparation of nutrient management plans. There may be capital expenditures associated with manure application equipment.

Risks:

The changes under consideration for effluent guidelines will reduce adverse water quality impacts caused by runoff from animal feeding operations, thereby reducing risks to aquatic habitat and public health.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	
Final Action	12/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

SAN No. 4153

Sectors Affected:

11221 Hog and Pig Farming; 11232 Broilers and Other Meat Type Chicken Production; 11231 Chicken Egg Production; 112112 Cattle Feedlots; 11212 Dairy Cattle and Milk Production; 11241 Sheep Farming; 11233 Turkey Production; 11292 Horse and Other Equine Production; 11239 Other Poultry Production

Agency Contact:

Jan Goodwin
Environmental Protection Agency
Water
4303
Washington, DC 20460
Phone: 202 260-7152
Fax: 202 260-7185
Email: goodwin.janet@epa.gov

Karen Metchis
Environmental Protection Agency
Water
4203
Washington, DC 20460
Phone: 202 260-7069
Fax: 202 260-1460
Email: metchis.karen@epa.gov

RIN: 2040–AD19

EPA

127. NATIONAL PRIMARY DRINKING WATER REGULATIONS: LONG-TERM 2 ENHANCED SURFACE WATER TREATMENT RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal goverments and the private sector.

Legal Authority:

40 USC 300g-1(b); SDWA 1412(b); 42 USC 300f; 42 USC 300g-1; 42 USC 300g-2; 42 USC 300g-3; 42 USC 300g-4; 42 USC 300g-5; 42 USC 300g-6; 42 USC 300j-4; 42 USC 300j-9; 42 USC 300j-11

CFR Citation:

40 CFR 141 to 142; 40 CFR 9

Legal Deadline:

None

Abstract:

The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) will control risk from microbial pathogens in drinking water. It is being developed simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR) which will address risk caused by the use of disinfectants in drinking water. This rule could affect all public water systems that use surface water as a source. Promulgating the LT2ESWTR and the Stage 2 DBPR as a paired rulemaking is necessary to ensure that adequate protection from microbial risk is maintained while EPA manages risk from disinfection byproducts. EPA is required to promulgate the Stage 2 DBPR by May 2002, under the 1996 Safe Drinking Water Act amendments. In developing the LT2ESWTR, EPA will analyze a significant body of new survey data on microbial pathogens in source and finished waters, as well as data on parameters which could serve as indicators of microbial risk. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, will provide a substantially more comprehensive and complete picture of the occurrence of waterborne pathogens than was available previously. EPA will also use significant new data on the efficiency of treatment processes for the removal and inactivation of microorganisms, as well as new information on the pathogenicity of certain pathogens, to determine effective regulatory requirements for controlling microbial risk. On March 30, 1999, EPA established a committee of stakeholders under the Federal Advisory Committee Act (FACA) to assist in the development of these rules. The FACA committee is scheduled to make recommendations

on rule options to EPA in September 2000.

Statement of Need:

The purpose of the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) is to reduce health risks posed by Cryptosporidium and other microbial pathogens in drinking water. Cryptosporidium is a protozoon which causes cryptosporidiosis, a severe gastrointestinal disease. While cryptosporidiosis is generally self-limiting in healthly individuals, it can be fatal for people with compromised immune systems. Cryptosporidium is removed to a degree by filtration but is highly resistant to conventional drinking water disinfectants, including chlorine and chloramines. EPA has recently collected a significant amount of data on occurrence of Cryptosporidium in drinking water sources through the Informaction Collection Rule (ICR) and ICR Supplemental Surveys. These data indicate that a subset of drinking water systems have an unacceptably high risk for Cryptosporidium in their treated water. The LT2ESWTR is intended to identify systems at high risk for Cryptosporidium through monitoring and prescribe an appropropriate level of additional treatment. In addition, the LT2ESWTR will be promulgated simultaneously with the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR). This will help to ensure that drinking water utilities do not compromise adequate microbial protection while they take steps to control DBPs.

Summary of Legal Basis:

Section 1412(b)(7)(A) of SDWA allows the Administrator to promulgate a national primary drinking water regulation that requires the use of a treatment technique in establishing a maximum contaminant level if the Adminsitrator makes a finding that it is not feasible to ascertain the level of the contaminant. The MCLG for Cryptosporidium is zero and it is not feasible for public water systems to measure Cryptosporidium concentrations in treated water. Consequently, under section 1412(b)(1)(A), the Administrator may establish a treatment technique for Cryptosporidium if this presents a meaningful opportunity for health risk reduction. In addition, section 1412(b)(2)(C) of SDWA, as amended in 1996, requires EPA to promulgate a Stage 2 Disinfectants/Disinfection Byproducts Rule no later than May 2002. Although the 1996 Amendments do not require EPA to finalize a Long Term 2 Enhanced Surface Water Treatment Rule along with the Stage 2 Disinfectants and Disinfection Byproducts Rule, Congress did emphasize the importance of ensuring proper balance between microbial and DBP risks and, therefore, EPA believes it is important to finalize these rules together.

Alternatives:

The major components of the LT2ESWTR are being developed by a committee convened under the Federal Advisory Committee Act (FACA). The FACA has considered various rule scenarios to reduce risk from Cryptosporidium. These scenarios have included treatment requirements that would apply to all systems, such as requiring all conventional plants to acheive 2-log inactivation of Crpytosporidium. Alternative scenarios have involved assigning systems to bins based on mean Crypto source water concentrations. Additional treatment requirements would then depend on the bin to which a system was assigned. Issues associated with the binning approach include: amount of monitoring necessary to assign systems to bins, appropriate Crypto concentrations to demarcate bin boundaries, and appropriate level of additional treatment for a given bin. EPA and the FACA are exploring analyses that evaluate the impact of these issues on costs and benefits. EPA has also considered options to reduce the impact on small systems.

Anticipated Cost and Benefits:

EPA estimates that the LT2ESWTR will have an annual economic impact of $100 million or more. The majority of people (approximately 67 percent) are served by public water systems that use a surface water or groundwater under the direct influence of surface water. Thus, a large number of people will benefit from the LT2ESWTR. In addition, EPA has recently identified UV light as a technology that can achieve high levels of Cryptosporidium inactivation at relatively low cost.

Risks:

Approximately 67 percent of consumers are served by drinking water systems that use surface water sources. Survey data indicate that Cryptosporidium is high prevalent in drinking water sources and current levels of treatment may not be adequate to control highly resistant pathogens like Cryptosporidium. Cryptosporidiosis is a potentially fatal disease in people with weak immune systems, such as infants, the elderly, people with AIDS, and people taking immune suppressing drugs like cancer and transplant patients. By requiring additional treatment for those systems with the highest concentrations of Cryptosporidium in their source waters, EPA expects to significantly reduce current risk.

Timetable:

Action	Date	FR Cite
NPRM	05/00/01	
Final Action	05/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

SAN No. 4341

Sectors Affected:

22131 Water Supply and Irrigation Systems

Agency Contact:

Thomas Grubbs
Environmental Protection Agency
Water
4607
Washington, DC 20460
Phone: 202 260-7270
Fax: 202 401-6135
Email: grubbs.thomas@epa.gov

Dan Schmelling
Environmental Protection Agency
Water
4607
Washington, DC 20460
Phone: 202 260-1439
Fax: 202 401-6135
Email: schmelling.dan@epa.gov

RIN: 2040–AD37

EPA

128. NATIONAL PRIMARY DRINKING WATER REGULATIONS: STAGE 2 DISINFECTANTS/DISINFECTION BYPRODUCTS RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal goverments and the private sector.

Legal Authority:

42 USC 300j-11; 42 USC 300g-5; 42 USC 300g-6; 42 USC 300j-4; 42 USC 300j-9; 42 USC 300g-4; 40 USC 300g-1(b); SDWA 1412(b); 42 USC 300f; 42 USC 300g-2; 42 USC 300g-3

CFR Citation:

40 CFR 141 to 142; 40 CFR 9

Legal Deadline:

Final, Statutory, May 31, 2002, SDWA 1412(b)(2)(A) imposes date for final rule promulgation.

Abstract:

The 1996 Safe Drinking Water Act Amendments require EPA to promulgate a Stage 2 Disinfectants/Disinfection Byproducts Rule (Stage 2 DBPR) by May 2002. EPA plans to propose this rule in May 2001. The regulation, along with a Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) that will be promulgated simultaneously, is intended to expand existing public health protections and address concerns about risk trade-offs between pathogens and disinfection byproducts. This rule could affect all public water systems that add a disinfectant to the drinking water during any part of the treatment process although the impacts may be limited to community water systems (CWSs) and nontransient noncommunity water systems (NTNCWSs). Promulgating the LT2ESWTR and the Stage 2 DBPR as a paired rulemaking is necessary to ensure that adequate protection from microbial risk is maintained while EPA manages risk from disinfection byproducts. In developing the Stage 2 DBPR, EPA will analyze a significant body of new survey data on source water quality parameters, treatment data and disinfection byproduct occurrence. This survey data, which was collected under the Information Collection Rule (ICR), Supplemental Surveys to the ICR, and additional research projects, will provide a substantially more comprehensive and complete picture of the occurrence of DBPs and microbiological pathogens than was available previously. EPA will also use new information on the health effects of exposure to DBPs to determine effective regulatory requirements for controlling risk. On March 30, 1999, EPA established a committee of stakeholders under the Federal Advisory Committee Act (FACA) to assist in the development of these rules. The FACA committee is scheduled to make recommendations on rule options to EPA in September 2000.

Statement of Need:

The purpose of the Stage 2 Disinfectants/Disinfection Byproducts Rule (DBPR) is to reduce potential health risks posed by disinfection byproducts (DBPs). Certain DBPs have been shown in laboratory tests to be carcinogens or to cause adverse reproductive and developmental health effects. In addition, epidemiology studies have indicated that exposure to chlorinated water may increase the risk of bladder cancer, miscarriage, and certain developmental defects. The Stage 2 DBPR is designed to reduce peak events in DBP exposure in order to mitigate these potential health risks.

Summary of Legal Basis:

Section 1412(b)(2)(C) of SDWA, as amended in 1996, requires EPA to promulgate a Stage 2 Disinfectants/Disinfection Byproducts Rule no later than May 2002. Although the 1996 Amendments do not require EPA to finalize a Long Term 2 Enhanced Surface Water Treatment Rule along with the Stage 2 Disinfectants and Disinfection Byproducts Rule, Congress did emphasize the importance of ensuring proper balance between microbial and DBP risks and, therefore, EPA believes it is important to finalize these rules together.

Alternatives:

The major components of the Stage 2 DBPR are being developed by a committee convened under the Federal Advisory Committee Act (FACA). The FACA has considered various rule scenarios to achieve reductions in disinfection byproduct exposure. These alternatives have included: decreasing the standard set in the Stage 1 DBPR (0.080 mg/L total trihalomethanes (TTHM) and 0.060 mg/L the sum of 5 haloacetic acids(HAA5)) by half and maintaining a running annual average compliance calculation; maintaining 80/60 TTHM/HAA5 standards but revising the compliance calculation to a stricter locational running annual average; setting the 80/60 TTHM/HAA5 standard as a never-to-be-exceeded maximum; and revising the standard for bromate which is currently 0.010 mg/L. EPA has also considered options to reduce the impact on small systems.

Anticipated Cost and Benefits:

EPA estimates that the Stage 2 DBPR will have an annual economic impact of $100 million or more. Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants and potentially exposed to DBPs. Thus, a large number of people will benefit from the Stage 2 DBPR.

Risks:

Over 200 million people are served by public water systems that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants. Due to the the large number of people exposed to DBPs, there is a substantial concern for any risks associated with DBPs that may impact public health. EPA estimates that the Stage 2 DBPR will decrease exposure to DBPs on average but more importantly, the rule will significantly reduce exposure to peak occurrences of DBPs.

Timetable:

Action	Date	FR Cite
NPRM	05/00/01	
Final Action	05/00/02	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Governmental Jurisdictions, Organizations, Businesses

Government Levels Affected:

Tribal, Federal, State, Local

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

SAN No. 4342

Sectors Affected:

22131 Water Supply and Irrigation Systems

Agency Contact:

Thomas Grubbs
Environmental Protection Agency
Water
4607
Washington, DC 20460
Phone: 202 260-7270
Fax: 202 401-6135
Email: grubbs.thomas@epa.gov

Jennifer McLain
Environmental Protection Agency
Water
4607
Washington, DC 20460
Phone: 202 260-0431
Fax: 202 401-6135
Email: mclain.jennifer@epa.gov

RIN: 2040–AD38

EPA

129. ● MINIMIZING ADVERSE ENVIRONMENTAL IMPACT FROM COOLING WATER INTAKE STRUCTURES AT EXISTING FACILITIES UNDER SECTION 316(B) OF THE CLEAN WATER ACT

Priority:

Economically Significant

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

33 USC 1311 CWA sec 301; 33 USC 1316 CWA sec 306; 33 USC 1326 CWA sec 316; 33 USC 1361 CWA sec 501

CFR Citation:

40 CFR 9, 122, 123, 124 and 125

Legal Deadline:

NPRM, Judicial, July 20, 2001, See additional information.

Abstract:

This proposed rulemaking will apply to the intake of water by existing facilities with cooling water intake structures. Section 316(b) of the Clean Water Act provides that any standard established pursuant to sections 301 or 306 of the Clean Water Act and applicable to a point source shall require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact. A primary purpose of the rulemaking is to minimize the impingement and entrainment of fish and other aquatic organisms by cooling water intake structures. Impingement refers to trapping fish and other aquatic life against cooling water intake screens. Entrainment occurs when aquatic organisms, eggs, and larvae are drawn into the cooling system through the heat exchanger, and then pumped back out, often with significant injury or mortality to the entrained organisms.

Statement of Need:

In the absence of the required national regulations, permit directors have implemented cooling water intake limitations incompletely and inconsistently. Literally tons of fish and other aquatic organisms may be cropped annually as a result of cooling water intake structures at a single large facility.

Summary of Legal Basis:

This action is required under consent decree in settlement of Cronin, et al. v. Reilly, 93 Civ. 0314 (AGS) (U.S.D.C., Southern District of New York, October 10, 1995).

Alternatives:

The analysis will cover various sizes and types of potentially regulated facilities. EPA is considering whether to regulate site-by-site, nationally, or on the basis of broad categories of water body types.

Anticipated Cost and Benefits:

Costs are undetermined. A qualitative assessment of benefits at several large facilities indicates the potential for significant benefits when large intakes are controlled. Costs and benefits are generally expected to be smaller at facilities that use smaller amounts of cooling water.

Risks:

Cooling water intake structures may pose significant risks for aquatic ecosystems.

Timetable:

Action	Date	FR Cite
NPRM	07/00/01	
Final Action	05/00/02	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4474

Split from RIN 2040-AC34.

Deadline for final action is the subject of settlement discussions.

Sectors Affected:

331111 Iron and Steel Mills; 331221 Cold-Rolled Steel Shape Manufacturing; 331222 Steel Wire Drawing; 33121 Iron and Steel Pipes and Tubes Manufacturing from Purchased Steel; 331315 Aluminum Sheet, Plate and Foil Manufacturing; 331521 Aluminum Die-Castings; 331524 Aluminum Foundries; 331525 Copper Foundries; 322121 Paper (except Newsprint) Mills; 32213 Paperboard Mills; 32411 Petroleum Refineries; 325311 Nitrogenous Fertilizer Manufacturing; 325199 All Other Basic Organic Chemical Manufacturing

Agency Contact:

Deborah Nagle
Environmental Protection Agency
Water
4303
Washington, DC 20460
Phone: 202 260-2656
Fax: 202 260-7185
Email: nagle.deborah@epa.gov

J. T. Morgan
Environmental Protection Agency
Water
4303
Washington, DC 20460
Phone: 202 260-6015
Fax: 202 260-7185
Email: morgan.james@epa.gov

RIN: 2040–AD62

EPA

130. ● CROSS-MEDIA ELECTRONIC REPORTING (ER) AND RECORDKEEPING RULE

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

PL 104-13; PL 105-277

CFR Citation:

40 CFR 3 (New); 40 CFR 9 (Revision)

Legal Deadline:

None

Abstract:

The Cross-Media Electronic Reporting (ER) and Recordkeeping Rule will

provide a uniform legal framework for paperless electronic reporting and recordkeeping, including electronic signature/certification, across EPA's environmental compliance programs. The rule will both remove current legal requirements for paper that create obstacles to electronic reporting and recordkeeping and provide for mechanisms to assure the legal validity and authenticity of electronic documents and associated electronic signatures, whether transmitted as reports or maintained as records. This rule is important because the legal and electronic signature issues remain the chief obstacle to implementation of paperless electronic reporting, and affect the overall enforceability of environmental programs both federally and under State delegation/ authorization. Also, the Government Paperwork Elimination Act of 1998 requirements and the Administrator's Reinventing Environmental Information (REI) Action Plan goal of universal ER availability by 2003 can only be met if this rulemaking has active participation by the AA-ships and moves on a fast track.

Statement of Need:

EPA is required by the Government Paperwork Elimination Act (GPEA) of 1998 to provide electronic reporting and recordkeeping as an option to its regulated community by 2003. To meet this deadline and comply with GPEA, the legal framework for electronic reporting must be in place by that time. The CROMERR rule is necessary to establish the legal framework to: (1) remove legal obstacles to electronic reporting and recordkeeping under most EPA regulations; and (2) assure that these electronic documents will have the same legal and evidentiary force as their paper counterparts. Electronic Reporting is also a capstone of the Administration's Reinventing Government Initiative and the Administrator's Integrated Information Initiative (I3).

Summary of Legal Basis:

(1) Government Paperwork Elimination Act (GPEA) of 1998. GPEA requires Federal agencies to provide electronic reporting and recordkeeping to its regulated community by 2003. (2) Electronic Signature National and Global Commerce Act (ESIGN), June 30, 2000. This law eliminates legal barriers to the use of electronic technology to form and sign contracts, collect and store documents, and send and receive notices and disclosures. ESIGN applies broadly to Federal statutes and regulations governing private sector (including business-to-business and business-to-consumer) activities. In general, it does not cover activities that are primarily governmental, which are governed by GPEA. ESIGN begins to take effect on October 1, 2000.

Alternatives:

The alternative to an EPA cross-media rule that applies to most compliance reports under 40 CFR, would be individual rulemakings by each of the program offices. EPA's past experience with such rulemakings has demonstrated that such a course of action would not bring EPA in compliance with GPEA by the 2003 deadline.

Timetable:

Action	Date	FR Cite
NPRM	11/00/00	
Final Action	11/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 4270

Fomerly listed as RIN 2020-AA41.

Agency Contact:

Evi Huffer
Environmental Protection Agency
Office of Environmental Information
2823
Washington, DC 20460
Phone: 202 260-8791
Fax: 202 401-0182
Email: huffer.evi@epa.gov

David Schwarz
Environmental Protection Agency
Office of Environmental Information
2823
Washington, DC 20460
Phone: 202 260-2710
Fax: 202 401-0182
Email: schwarz.david@epa.gov

RIN: 2025–AA07

EPA

FINAL RULE STAGE

131. REVISION TO 40 CFR 35 SUBPART A AND PROMULGATION OF PERFORMANCE PARTNERSHIP (STATE) GRANT REGULATION

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

PL 104-134; PL 105-65

CFR Citation:

40 CFR 35

Legal Deadline:

None

Abstract:

This proposed regulation: (1) updates, clarifies, and streamlines requirements governing environmental program grants; (2) establishes requirements for the new Performance Partnership Grant (PPG) program; and (3) establishes requirements for grant programs that began after the original rule was published. (A regulation governing environmental program grants to Indian tribes and tribal consortia is published elsewhere in this issue of the Federal Register.)

Statement of Need:

Since EPA was formed in 1970, State capacity and responsibility for implementing environmental and public health protection programs has grown steadily. Until 1996, State and interstate agencies could receive EPA assistance in carrying out their environmental programs only through a variety of categorical environmental grants, such as grants for water pollution control, air pollution control, and hazardous substance control. Meanwhile, environmental problems and their solutions have grown more complex and solutions to these complex problems often crossed EPA program lines. In light of this complexity, State and EPA leaders recognized that continued environmental progress could be best achieved if EPA and States worked together more effectively as partners

and environmental programs were made more flexible in terms of their coverage.

In response, EPA asked Congress for new authority that would provide that needed flexibility. In 1996, Congress authorized the award of Performance Partnership Grants (PPGs), in which State and interstate agencies can choose to combine two or more environmental program grants.

This proposed rule will implement the PPG program which promotes State-EPA collaboration; provides opportunities for innovation; and reduces paperwork. EPA expects the rule will foster joint planning and priority-setting by explicitly requiring that State priorities and needs be considered, along with national and regional guidance, in negotiating grant work plans, consistent with the National Environmental Performance Partnership System (NEPPS). Under this rule, a State can choose to organize its grant work plans in accord with environmental goals and objectives or in other new ways rather than using categories predefined by EPA. The length of a grant budget period will be negotiable. These opportunities afforded by the PPG program and this rule are available to all States.

This rule accommodates all potential variations in how EPA and individual States work to build partnerships. The rule also minimizes duplicative effort by allowing for multiple uses of information or processes wherever appropriate. The regulation advances ongoing efforts to build more effective State-EPA partnerships and to improve environmental conditions by providing States with increased flexibility to direct resources where they are needed most to address environmental and public health needs.

Summary of Legal Basis:

Not required by law or court order.

Alternatives:

EPA can continue to award PPGs under guidance prepared by the agency and announced in the Federal Register.

Anticipated Cost and Benefits:

The rule does not result in any new costs. It is expected to allow cost and administrative savings for States by reducing the amount of grant paperwork and by simplifying accounting requirements that do not require recipients to account for expenditures in accordance with their original funding sources. With PPGs, recipients can negotiate work plans with EPA that direct Federal funds where the recipients need them most to address environmental and public health problems. Recipients can also try new multimedia approaches and initiatives, such as children's health protection programs, multimedia inspections, compliance assistance programs, and ecosystem management, that were difficult to fund under traditional categorical grants.

Timetable:

Action	Date	FR Cite
NPRM	07/23/99	64 FR 63731
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State, Local

Procurement:

This is a procurement-related action for which there is no statutory requirement. There is no paperwork burden associated with this action.

Additional Information:

SAN No. 3736

Agency Contact:

Scott McMoran
Environmental Protection Agency
Administration and Resources Management
3903R
Washington, DC 20460
Phone: 202 564-5376

RIN: 2030–AA55

EPA

132. REVISION TO 40 CFR 35 SUBPART A AND PROMULGATION OF PERFORMANCE PARTNERSHIP (TRIBAL) GRANT RULE

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

PL 104-134; PL 105-65

CFR Citation:

40 CFR 35

Legal Deadline:

None

Abstract:

This proposed regulation will: (1) update, clarify, and streamline requirements governing environmental program grants; (2) establish requirements for the new Performance Partnership Grant (PPG) program; and (3) establish requirements for grant programs that were developed after the original rule was published. (EPA is also issuing a regulation governing environmental program grants to State and interstate agencies.)

Statement of Need:

This regulation provides a tribal-specific subpart which is intended to be easy to use; optimizes the administration of tribal assistance programs through increased flexibility; and removes procedural impediments to effective environmental programs for Indian tribes.

Since EPA was formed in 1970, tribal capacity and responsibility for implementing environmental and public health protection programs has grown steadily. Until 1996, tribes and intertribal consortia could receive EPA assistance in carrying out their environmental programs only through a variety of categorical environmental grants, such as grants for water pollution control, air pollution control, and safe drinking water. During that time, environmental problems and their solutions grew more complex and solutions to those complex problems often crossed EPA program lines. In light of this complexity, tribal and EPA leaders recognized that continued environmental progress could be best achieved if EPA and the tribes worked together more effectively as partners and environmental programs were made more flexible in terms of their coverage.

In response, EPA asked Congress for new authority that would provide that needed flexibility. In 1996, Congress authorized the award of Performance Partnership Grants (PPGs), in which tribes and intertribal consortia can choose to combine two or more environmental program grants.

This proposed rule will implement the PPG program which promotes tribal-EPA collaboration; provides opportunities for innovation; and reduces paperwork. EPA expects the rule will foster joint planning and priority-setting by explicitly requiring that tribal priorities and needs be considered, along with national and

regional guidance, in negotiating grant work plans, consistent with the National Environmental Performance Partnership System (NEPPS). Under this rule, a tribe can choose to organize its grant work plans in accord with environmental goals and objectives or in other new ways rather than using categories predefined by EPA. The length of a grant budget period will be negotiable. These opportunities afforded by the PPG program and this rule are available to all tribes which receive grants under more than one EPA environmental program.

This rule accommodates all potential variations in how EPA and individual tribes work to build partnerships. The rule also minimizes duplicative effort by allowing for multiple uses of information or processes wherever appropriate. The regulation advances ongoing efforts to build more effective tribal-EPA partnerships and to improve environmental conditions by providing tribes with increased flexibility to direct resources where they are needed most to address environmental and public health needs.

Summary of Legal Basis:

Not required by law or court order.

Alternatives:

EPA can continue to award PPGs under guidance prepared by the agency and announced in the Federal Register.

Anticipated Cost and Benefits:

The rule does not result in any new costs. It is expected to achieve cost and administrative savings for tribes by reducing the amount of grant paperwork and by simplifying accounting requirements that do not require recipients to account for expenditures in accordance with their original funding sources. With PPGs, recipients can negotiate work plans with EPA that direct Federal funds where the recipients need them most to address environmental and public health problems. Recipients can also try new multimedia approaches and initiatives, such as children's health protection programs, multimedia inspections, compliance assistance programs, and ecosystem management, that were difficult to fund under traditional categorical grants.

Risks:

There are no known risks.

Timetable:

Action	Date	FR Cite
NPRM	07/23/99	64 FR 63732
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, Tribal

Procurement:

This is a procurement-related action for which there is no statutory requirement. There is no paperwork burden associated with this action.

Additional Information:

SAN No. 4128

Agency Contact:

Michelle McClendon
Environmental Protection Agency
Administration and Resources Management
3903R
Washington, DC 20460
Phone: 202 564-5357
Fax: 202 565-2470
Email: mcclendon.michelle@epa.gov

RIN: 2030–AA56

EPA

133. IMPLEMENTATION OF OZONE AND PARTICULATE MATTER (PM) NATIONAL AMBIENT AIR QUALITY STANDARDS (NAAQS) AND REGIONAL HAZE REGULATIONS

Priority:

Other Significant

Legal Authority:

Clean Air Act, title I

CFR Citation:

40 CFR 50; 40 CFR 51; 40 CFR 52; 40 CFR 81

Legal Deadline:

None

Abstract:

On July 18, 1997, EPA issued new, updated air quality standards for ozone (62 FR 38856) and particulate matter (PM) (62 FR 38652). Pursuant to President Clinton's implementation strategy as outlined in a July 16, 1997 memorandum to EPA Administrator Carol Browner, EPA had been developing guidance and rules for sensibly and cost-effectively meeting the new standards. On November 17, 1998, EPA made available for comment proposed implementation guidance on implementing the revised ozone and PM NAAQS and regional haze program. On May 14, 1999, however, the U.S. Court of Appeals for the D.C. Circuit issued an opinion concerning the revised ozone and particulate matter NAAQS (American Trucking Assoc., Inc. et al. v. USEPA, No. 97-1440 (May 14, 1999)) in which the Court stated, among other things, that the revised 8-hour ozone standard ''cannot be enforced.'' The Court also vacated the revised PM10 NAAQS and remanded the PM2.5 NAAQS. On June 28, 1999, EPA requested a rehearing of the case before the Court, but the request was denied. The Department of Justice then filed a petition in January 2000 seeking U.S. Supreme Court review, and the Court subsequently agreed to review the case. EPA expects a decision from the Supreme Court in early to mid-2001. Until the appeals process is exhausted, EPA does not intend to issue final guidance for implementation of the standards affected by the Appeals Court's decision. Once the Supreme Court renders a decision, EPA will determine what actions may be appropriate. Meanwhile, to assure that areas were not left without an air-quality standard, EPA took action on 7/6/00 to reinstate the previous 1-hr standard in approximately 3000 counties across the United States. EPA is also developing guidelines for determining Best Available Retrofit Technology (BART) under the Regional Haze Regulations through a formal rulemaking proposal (see SAN 4450 in today's regulatory agenda).

Statement of Need:

Development of programs for ozone and PM are necessary to implement any revised NAAQS under title 1 of the Clean Air Act.

Summary of Legal Basis:

Title I of the Clean Air Act

Alternatives:

This entry comprises the set of actions the Agency plans to take to implement the new ozone and fine particulate standards. The major alternative facing the Agency was whether to implement the standards strictly on a state-by-state basis, as has been the norm in the past, or to take Federal action to address the fact that emissions from one State affect the ability of other States to achieve the standards. The other major set of alternatives involved various possible strategies for infrastructure design, such as the designations of nonattainment areas and the requirements that will apply to them. The major issues in this

area were settled by the July 1997 issuance of a Presidential Directive setting out a flexible implementation policy, the elements of which are summarized in the abstract above.

Anticipated Cost and Benefits:

EPA prepared a regulatory impact analysis (RIA) for the final ozone and PM NAAQS, as well as the regional haze reduction program.

Risks:

The risks addressed by this implementation plan are those of not attaining the National Ambient Air Quality Standards for Ozone and Particulate Matter.

Timetable:

Action	Date	FR Cite
ANPRM	12/13/96	61 FR 65764
Notice Proposed Policy	12/13/96	61 FR 65752
NPRM Regional Haze	07/31/97	62 FR 41138
Notice Review Schedule for PM2.5 Standard	10/23/97	62 FR 55201
Final Rule - Areas Meeting 1-Hour Ozone Standard	06/05/98	63 FR 31013
Final Rule - Additional Areas Meeting 1-Hour Ozone Standard	07/22/98	63 FR 39432
Draft Guidance - Implementation Planning	11/17/98	63 FR 65593
Final Rule - Additional Areas Meeting 1-Hour Ozone NAAQS: 96-98 Data	06/09/99	64 FR 30911
Final Rule - Regional Haze	07/01/99	64 FR 35713
Final Action - Reinstatement of 1-Hour Standard	07/20/00	65 FR 45182
Final Guidance on Hold Pending Court Action	To Be	Determined

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

State

Additional Information:

SAN No. 3553

Agency Contact:

Denise Gerth
Environmental Protection Agency
Air and Radiation
MD-15
Research Triangle Park, NC 27711
Phone: 919 541-5550
Fax: 919 541-0824
Email: gerth.denise@epa.gov

John Silvasi
Environmental Protection Agency
Air and Radiation
MD-15
Research Triangle Park, NC 27711
Phone: 919 541-5666
Fax: 919 541-0824
Email: silvasi.john@epa.gov

RIN: 2060–AF34

EPA

134. ENVIRONMENTAL RADIATION PROTECTION STANDARDS FOR YUCCA MOUNTAIN, NEVADA

Priority:

Other Significant

Legal Authority:

Energy Policy Act sec 801

CFR Citation:

40 CFR 197

Legal Deadline:

NPRM, Statutory, August 1, 1996.

Abstract:

This rulemaking is in response to section 801 of the Energy Policy Act of 1992 which directs the Administrator to promulgate public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of in the repository at the Yucca Mountain site. The only regulated entity is the U.S. Department of Energy.

Statement of Need:

In 1985, the Agency issued generic standards for the management and disposal of spent nuclear fuel and high-level radioactive waste. The Nuclear Waste Policy Amendments Act of 1987 mandated the study of Yucca Mountain, Nevada, to determine its suitability to be a repository for spent nuclear fuel and high-level radioactive waste. The Waste Isolation Pilot Plant Land Withdrawal Act of 1992 exempted Yucca Mountain from coverage under the 1985 generic standards. Concurrently, the Energy Policy Act of 1992 gave EPA the responsibility of setting site-specific, radiation-protection standards for Yucca Mountain.

Summary of Legal Basis:

The legal authority is derived from the Energy Policy Act of 1992.

Alternatives:

Since this action is legally mandated, there are no alternatives.

Anticipated Cost and Benefits:

Since the potential cost is dependent upon several factors whose determination has not yet been made, a precise assessment of the economic impact of the rulemaking is not possible at this time. Likewise, the benefits, i.e., the adverse effects averted (which are required to complete a cost-benefit analysis), cannot be determined in a meaningful manner at this time since the effect of these standards is to avert potential adverse health effects that may occur during very long periods into the future and are, therefore, quantifiable only with a high degree of uncertainty.

Risks:

The maximum allowable lifetime risk which would be allowed under these standards is 3 chances in 10,000 in contracting a fatal cancer, which is the upper end of what the Agency deems an acceptable risk. In addition, we have proposed a seperate protection for ground water resources at levels established by the Safe Drinking Water Act.

Timetable:

Action	Date	FR Cite
NPRM	08/27/99	64 FR 46976
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Additional Information:

SAN No. 3568

Agency Contact:

Ray Clark
Environmental Protection Agency
Air and Radiation
6608J
Washington, DC 20460
Phone: 202 564-9198
Fax: 202 565-2065
Email: clark.ray@epa.gov

RIN: 2060–AG14

EPA

135. CONSOLIDATED FEDERAL AIR RULE FOR THE SYNTHETIC ORGANIC CHEMICAL MANUFACTURING INDUSTRY

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 7401 et seq

CFR Citation:

40 CFR 60; 40 CFR 61; 40 CFR 63; 40 CFR 65

Legal Deadline:

None

Abstract:

Over the past 25 years, EPA has issued a series of national air regulations, many of which affect the same facility. Each rule has emission control requirements as well as monitoring, recordkeeping, and reporting requirements. All existing Federal air rules applicable to an industry sector will be reviewed to determine whether their provisions can be consolidated into a single new rule. Affected industries, State agencies, and other stakeholders will be consulted to identify duplicative provisions. The chemical industry and State representatives have agreed to work on a pilot project with EPA's air programs to explore this approach. If the approach is successful with the chemical industry, it may be expanded to air rules for other industry sectors.

Statement of Need:

Both industry and regulatory agencies have expressed a great desire to streamline and simplify rules. This rule streamlines and simplifies by consolidating and collapsing the numerous Federal rules that apply to the chemical industry, with resulting improved compliances.

Summary of Legal Basis:

Clean Air Act sections 111 and 112

Alternatives:

The main alternative is to do nothing and let the many rules with their many provisions remain the only compliance mechanism.

Anticipated Cost and Benefits:

This rule will result in considerable savings to the affected industry. There is significant burden reduction associated with recordkeeping and reporting. The rule will be easier to follow and understand. There will be no change in applicability of the rules being consolidated.

Risks:

This rulemaking deals with consolidated reporting to simplify existing rules. The risks addressed by each of these existing rules were addressed in those individual rulemakings.

Timetable:

Action	Date	FR Cite
NPRM	10/28/98	63 FR 57748
Final Action	10/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Additional Information:

SAN No. 3748

Agency Contact:

Susan Wyatt
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-5674
Fax: 919 541-0942
Email: wyatt.susan@epa.gov

Rick Colyer
Environmental Protection Agency
Air and Radiation
MD-13
Research Triangle Park, NC 27711
Phone: 919 541-5262
Fax: 919 541-0942
Email: colyer.rick@epa.gov

RIN: 2060–AG28

EPA

136. HEAVY-DUTY ENGINE EMISSION STANDARDS AND DIESEL FUEL SULFUR CONTROL REQUIREMENTS

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

Not Yet Determined

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

This rulemaking will set new quality requirements for fuel used in diesel engines in order to bring about large environmental benefits through the enabling of a new generation of diesel emission control technologies. Improving the quality of diesel fuel will enable advanced technologies for diesel emission control. These advanced sulfur-sensitive technologies have the potential to reduce diesel engine NOx emissions by 75 percent and PM emissions by 80 percent or more. A key approach taken in developing the ''Tier II'' standards (Tier II Light-Duty Vehicle and Light-Duty Truck Emission Standards and Gasoline Sulfur Standards — see RIN 2060-AI23 in this Regulatory Plan) was ''fuel-neutrality'' — applying standards equally to diesel- and gasoline-powered vehicles. Reducing sulfur levels in highway diesel fuel will help facilitate development of diesel-powered vehicles that meet these standards. This rulemaking will also set new heavy duty NOx and PM engine standards. Low-sulfur diesel fuel is needed so that advanced technology for diesel engines will be available to meet new more stringent standards. There are also additional air quality benefits such as particulate matter and sulfate reductions associated with reducing sulfur levels in diesel fuel.

Statement of Need:

Ozone and particulate pollution pose a serious threat to the health and well-being of millions of Americans and a large burden to the U.S. economy. This rulemaking will address additional national control measures to reduce emissions, including emissions of nitrogen oxides, hydrocarbons, and

particulate matter, from heavy-duty diesel engines, and will also require reduced sulfur levels in diesel fuel, in order to protect the public health and welfare.

Summary of Legal Basis:

42 USC 7521; 42 USC 7545

Alternatives:

EPA analyzed several alternatives. These are discussed in the notice of proposed rulemaking.

Anticipated Cost and Benefits:

EPA's analysis of the costs and emission reductions is described in the proposed rule.

Risks:

The risks addressed by this program are primarily those associated with nonattainment of the National Ambient Air Quality Standards for ozone and particulate matter. There are also serious public health and environmental problems associated with toxic air pollution, acid rain, reduced visibility, and nitrogen loading of estuaries.

Timetable:

Action	Date	FR Cite
ANPRM	06/16/99	64 FR 32209
NPRM	06/02/00	65 FR 35429
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Federalism:

Undetermined

Additional Information:

SAN No. 4355

Agency Contact:

Paul Machiele
Environmental Protection Agency
Air and Radiation
Ann Arbor, MI 48105
Phone: 734 214-4264
Fax: 734 214-4050
Email: machiele.paul@epa.gov

Don Kopinski
Environmental Protection Agency
Air and Radiation
OMS EPCD
Ann Arbor, MI 48105
Phone: 734 214-4229
Fax: 734 214-4816
Email: kopinski.donald@epa.gov

RIN: 2060–AI69

EPA

137. PLANT-INCORPORATED PROTECTANTS; FIFRA RULE AND FFDCA TOLERANCE ACTIONS

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

21 USC 346(a) et seq; 7 USC 136 et seq

CFR Citation:

40 CFR 152.20; 40 CFR 174

Legal Deadline:

None

Abstract:

Substances that plants produce to protect themselves against pests are pesticides under FIFRA if humans intend to use them to destroy, prevent, repel or mitigate any pest. The Agency designates these substances, along with the genetic material necessary to produce them, plant-pesticides. This rulemaking will change the name of these pesticides to plant-incorporated protectants and will clarify the relationship between plants and plant-incorporated protectants and exempt conventional breeding. It will establish a new part in title 40 of the CFR, part 174, which consolidates regulations specific for plant-pesticides in one part of the CFR. The proposed consolidation is expected to benefit the public by providing greater focus, enhanced clarity and ease of use. These actions may reduce burden on both the regulated community and EPA.

Statement of Need:

In 1986, the Federal Government announced in the Coordinated Framework for Regulation of Biotechnology (51 FR 23302 June 26, 1986) that it would use existing laws in a coordinated fashion to regulate products of biotechnology. Thus, the EPA, which is responsible for regulating the use of pesticides, would be responsible for products of biotechnology that are to be used as pesticides. The rule is part of a program to implement fully the Coordinated Framework. The rule is needed to ensure the safe application of biotechnology to produce pesticidal products. Some of the pesticides produced and used in the living plant (plant-incorporated protectants) may pose the same types of environmental and human health risks as do the chemical, biochemical, and microbial pesticides that are regulated by EPA. Other risks may be unique to plant-incorporated protectants. On the other hand, all plant varieties have some ability to resist pests and a frequent aim of traditional plant breeding is development of plant varieties for pest resistance. Each of these abilities is linked to plant-incorporated protectants, if humans intend to use the ability to prevent, destroy, repel or mitigate pests. Without the exemption in the rule, all plant-incorporated protectants would have to be registered under FIFRA. EPA evaluated for risk plant-incorporated protectants in the categories described in the options set forth in the economic analysis. EPA was able to determine that those plant-incorporated protectants exempted under option 3 of this economic analysis warranted exemption at this time.

Summary of Legal Basis:

The EPA regulates pesticides in the United States. The principal legal authority is established by the FIFRA. This rule is promulgated under the authority of FIFRA section 3 and section 25(a) and (b) (7 U.S.C. 136a and 136w(a) and (b)). FIFRA section 3(a) provides, with some exceptions, that no person may distribute or sell in the United States any pesticide that is not registered under the Act (7 U.S.C. 136(a)). FIFRA section 2(u) defines ''pesticide'' as: ''(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for

use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer'' (7 U.S.C. 136(u)). Under FIFRA section 2(t), the term ''pest'' includes ''(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism'' with certain exceptions (7 U.S.C. 136(t)) Before EPA may register a pesticide under FIFRA, the applicant must show that the pesticide ''when used in accordance with widespread and commonly recognized practice, . . . will not generally cause unreasonable adverse effects on the environment'' (7 U.S.C. 136(a)(c)(5)). Section 25(b)(2) of FIFRA allows EPA to exempt, by regulation, any pesticide from some or all the requirements of FIFRA, if the pesticide is of a character which is unnecessary to be subject to FIFRA in order to carry out the purposes of that Act (7 U.S.C. 136w(b)(2)). EPA interprets FIFRA section 25(b)(2) to authorize EPA to exempt a pesticide or category of pesticides that EPA determines poses a low probability of risk to the environment, and that is not likely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight under FIFRA.

Alternatives:

Four alternatives are analyzed in this economic analysis:: (1) an option with a broad range of exemptions that removes three more categories of plant-incorporated protectants than the rule from the FIFRA requirements; (2) an option that exempts a more narrow scope of plant-incorporated protectants than option 1 but more categories than option 3; (3) an option representing the exemption promulgated in the final rule; and (4) an option with no exemptions, i.e., regulating all plant-incorporated protectants. The alternatives analyzed in this economic analysis (EA) differ from the proposed EA in the number and types of submissions of plant-incorporated protectants that the Agency anticipates will be received for registration annually over the next 10 years. The projected data requirements associated with the various types of plant-incorporated protectants in the various alternative case studies have also been recalculated in light of the Agency's experience with plant-incorporated protectants since the proposed EA was developed in 1994. The exemptions in some of the options differ slightly from the options in the proposal in order to be consistent with the exemption in the rule.

Anticipated Cost and Benefits:

The total direct compliance costs for option 3, which represents the scope of EPA's final rule, are estimated to be $2.4 million for year 1 increasing to $7.9 million in year 10. The rule exempts one specific category of plant-incorporated protectants from FIFRA requirements because EPA assessments determined that plant-incorporated protectants in this category present low probability of risk to the environment and are not likely to pose unreasonable adverse effects to the environment even in the absence of regulatory oversight. The exemption may lower cost to industry and the Agency while providing safety and assurance to the public and protection of the environment. The rule allows the Agency to focus resources on the plant-incorporated protectants that may present a higher potential for risk to human health or the environment, especially those with novel exposures. Industry may also benefit from greater certainty regarding the regulatory status of their plant-incorporated protectants. With the promulgation of the Rule, affected firms will be able to plan ahead for timely product development and commercialization.

Risks:

With the plant-incorporated protectants not exempted by the rule, there is a possibility of new dietary exposures. For example, a qualitatively different exposure could occur if a food plant was modified to produce a pesticidal substance derived from a nonfood source (e.g., microorganisms or insects). Modern biological and genetic techniques enable developers to greatly expand the range of sources of genetic information introduced into plants and thus into foods, and thus increase the possibility that substances significantly different from a substance historically consumed safely might be in food. With plant-incorporated protectants for which there is no record of prior significant human exposure, there may be no documentation demonstrating that residues of such plant-incorporated protectants consumed in food will not have adverse or toxic effects. Also to be considered is the potential for risk to be associated with quantitative changes in levels of substances that occur naturally in plants, generally at very low levels in the food portion, that are toxic when ingested. These same considerations apply in terms of environmental risk and new or significantly different exposures of nontarget organisms to the pesticide. Another environmental risk consideration associated with plant-incorporated protectants is the possible transfer through outcrossing of an introduced plant-incorporated protectant, from a crop plant to a cultivated or wild relative.

Timetable:

Action	Date	FR Cite
NPRM	11/23/94	59 FR 60496
Supplemental NPRM	07/22/96	61 FR 37891
Supplemental NPRM	05/16/97	62 FR 27132
Supplemental NPRM Request for Comment on Alternate Name	04/23/99	64 FR 19958
Supplemental NPRM	12/00/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

SAN No. 2684

Agency Contact:

Elizabeth Milewski
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7201
Washington, DC 20460
Phone: 202 260-3573
Fax: 202 260-0949
Email: milewski.elizabeth@epa.gov

Janet Andersen
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7501W
Washington, DC 20460
Phone: 703 308-8712
Email: andersen.janet@epa.gov

RIN: 2070–AC02

EPA

138. GROUNDWATER AND PESTICIDE MANAGEMENT PLAN

Priority:

Economically Significant

Legal Authority:

7 USC 136(a) FIFRA sec 3; 7 USC 136(w)

CFR Citation:

40 CFR 152.170

Legal Deadline:

None

Abstract:

This regulation would establish Pesticide Management Plans (PMPs) as a new regulatory requirement for certain pesticides. Unless a State or tribal authority has an EPA-approved plan specifying risk-reduction measures, use of the chemical would be prohibited. The rule would also specify procedures and deadlines for development, approval and modification of plans by States and tribal authorities.

Statement of Need:

EPA proposed to make specific pesticides subject to the provisions of EPA-approved Pesticide Management Plans (PMPs) because of their strong groundwater contamination potential. The rule intends to establish PMPs as an other regulatory restriction and to define the minimum requirements and procedures for developing, approving and managing PMPs. Upon promulgation of this rule, the labels of the designated pesticides will be changed to require use in conformance with EPA-approved PMPs, and to prohibit sale and use in States or Indian Country without such approved Plans (after a period allowed for development and EPA review of these Plans). A PMP is a State's or tribe's commitment to EPA and the public to manage the use of a certain pesticide in such a way as to avoid unreasonable risks to groundwater that would otherwise warrant cancellation of the use. An approved plan will embody a combination of educational, scientific, and regulatory tools to fulfill the State's groundwater protection goals, developed through a process of public participation. A plan will include a process for disseminating this information to pesticide users and marketers, and for monitoring the effectiveness of the plan through the development of appropriate indicators of environmental improvement and/or protection.

Summary of Legal Basis:

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) generally requires EPA to regulate pesticide use in such a manner as to prevent unreasonable risks to human health and the environment. Specifically, 7 USC 136a authorizes EPA to prescribe by regulation ''other regulatory restrictions'' for pesticides that may generally cause unreasonable risks to the environment (such as those that are associated with groundwater contamination potential) without those restrictions.

Alternatives:

This rule is a direct outgrowth of the Pesticides and Groundwater Strategy, published in October 1991 (after extensive consultation with States, localities, and other affected stakeholders). In publishing the strategy EPA conducted an analysis of three different alternatives to the regulation of pesticides' groundwater risks. One option was to rely exclusively on orthodox national-level pesticide regulatory tools (tantamount to a ''baseline''), which would entail tolerating or remediating a certain level of groundwater contamination. At the other extreme, outright cancellation of candidate pesticides with significant groundwater contamination potential was considered to provide full assurance that no further groundwater contamination would occur (taking into account the high economic losses due to the removal of the pesticide from the market). The analysis concluded that a ''partnership'' approach, providing a mechanism for more tailored management of pesticide use (i.e., taking into account the prevailing influence of highly variable hydrologic ''sensitivity'' factors), would be simultaneously a more effective and least costly alternative.

Anticipated Cost and Benefits:

EPA anticipates four categories of costs entailed in requiring PMPs. Federal Program Costs are those of administering groundwater protection activities, such as the review of State or tribal proposals. State Program Costs entail both capital and annual costs. Registrant and user impacts are the economic losses ascribed to the reduced use of the classified pesticides, as well as the costs (to the registrants) of complying with Federal, State and tribal provisions. Benefits accrue from the reduced levels of pesticide residues in groundwater, and a corresponding reduction in: (1) human and ecological risk (see below); and (2) threats to the economic and intrinsic values of the groundwater resource. Significant uncertainties attend the quantification of these benefits, however.

Risks:

The pesticides under consideration are those most frequently detected (sometimes at concentrations exceeding health-based reference points) of currently-registered Pesticides, and display physical and chemical characteristics associated with a ground-water contamination potential. The level of potential contamination (and related risk to both human health and the environment) represent a potential unreasonable risk to the environment in the absence of local management measures. State management measures are expected to avert these risks substantially. Because the Food Quality Protection Act (FQPA) requires that EPA consider drinking water as part of dietary exposure, the Agency is analyzing implications for this regulation.

Timetable:

Action	Date	FR Cite
NPRM	06/26/96	61 FR 33259
Notice of Availability Regarding Metolachlor	02/23/00	65 FR 8925
Supplemental NPRM - Notice of Availability & Extension of Comment Period	03/24/00	65 FR 15885
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Tribal

Additional Information:

SAN No. 3222

Sectors Affected:

9241 Administration of Environmental Quality Programs

Agency Contact:

Arthur-Jean B. Williams
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7506C
Washington, DC 20460
Phone: 703 305-5239
Fax: 703 308-3259
Email: williams.arty@epa.gov

Jean Frane
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7506C
Washington, DC 20460
Phone: 703 305-5944
Email: frane.jean@epa.gov

RIN: 2070–AC46

EPA

139. TSCA INVENTORY UPDATE RULE AMENDMENTS

Priority:

Other Significant

Legal Authority:

15 USC 2607(a) TSCA 8(a)

CFR Citation:

40 CFR 710

Legal Deadline:

None

Abstract:

This action would amend the current Toxic Substances Control Act (TSCA) Inventory Update Rule (IUR) to require chemical manufacturers to report to EPA data on exposure-related information and the industrial and consumer end uses of chemicals they produce or import. Currently, EPA requires chemical manufacturers to report the names of the chemicals they produce, as well as the locations of manufacturing facilities and the quantities produced. About 3,000 facilities reported data on about 9,000 unique chemicals during the last reporting cycle under the IUR. Data obtained would be used by EPA and others to: better understand the potential for chemical exposures; screen the chemicals now in commerce and identify those of highest concern; establish priorities and goals for their chemical assessment, risk management and prevention programs, and monitor the programs' progress; encourage pollution prevention by identifying potentially safer substitute chemicals for uses of potential concern; and enhance the effectiveness of chemical risk communication efforts. Additionally, EPA will consider other amendments to the IUR. These include removing the inorganic chemicals exemption; providing the information to better assess and manage risks of inorganic chemicals; improving the linkages of IUR data to other data sources to enhance the data's usefulness; and altering the confidential business information (CBI) claim procedures to reduce the frequency of CBI claims, allowing the public greater access to relevant information on toxic chemicals. EPA has held meetings with representatives of the chemical industry, environmental groups, environmental justice leaders, labor groups, State governments and other Federal agencies to ensure public involvement in the TSCA Inventory Update Rule Amendments Project.

Statement of Need:

There are more than 75,000 chemicals in commerce listed on the TSCA Inventory. EPA faces the challenge of sorting through these chemicals to identify the ones of most concern, then taking the appropriate steps to mitigate unreasonable risks of those chemicals. The current IUR collects some key data, such as production volume, used to identify the chemicals of most concern. However, other exposure-related information is essential to more accurately identify the chemicals with the greater risk potential. Information on how a chemical is manufactured, processed, and used is needed to determine possible exposure routes and scenarios of these chemicals. This action will propose to modify the inventory update process to collect the exposure-related data necessary for an effective TSCA Inventory Screening program; the information will be collected in a format that makes the information easy to use to screen thousands of chemicals. A national report will make data collected via the amended IUR publicly available. This report will not contain any information claimed to be confidential.

Summary of Legal Basis:

Toxic Substances Control Act (TSCA) section 8

Alternatives:

Although data on the use of specific chemicals can be found in varying sources, there is no national, comprehensive, current searchable database providing consistent information on a wide variety of chemicals. EPA has examined alternate sources of the information including State information, Federal databases and privately collected information. EPA can find no information comparable to the data anticipated to be collected through amendments to the IUR.

Anticipated Cost and Benefits:

EPA anticipates costs of this action to be well under $100 million for the first year of reporting. Total costs of this action depend on the amendments to IUR that are contained in a proposed rule. The amended IUR will assist EPA in screening chemicals in commerce and identifying those of highest concern; establishing priorities and goals for chemical assessment, risk management and prevention programs and to monitor their progress; identifying potentially safer substitute chemicals for uses of potential concern; and enhancing the effectiveness of chemical risk communication efforts.

Risks:

This action will secure data on describing how chemicals in commerce are used; this data is essential to determine possible exposure routes and scenarios. Using these exposure estimates, EPA's toxics program will be able to better focus on chemical risks of most concern.

Timetable:

Action	Date	FR Cite
NPRM	08/26/99	64 FR 46771
Notice Comment Extension	10/22/99	64 FR 56998
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Additional Information:

SAN No. 3301

Sectors Affected:

324 Petroleum and Coal Products Manufacturing; 325 Chemical Manufacturing

Agency Contact:

Susan Krueger
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7406
Washington, DC 20460
Phone: 202 260-1713
Fax: 202 260-1661
Email: krueger.susan@epa.gov

Robert Lee
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7406
Washington, DC 20460
Phone: 202 260-0676
Fax: 202 260-1661
Email: lee.robert@epa.gov

RIN: 2070–AC61

EPA

140. LEAD; IDENTIFICATION OF DANGEROUS LEVELS OF LEAD PURSUANT TO TSCA SECTION 403

Priority:

Economically Significant

Legal Authority:

15 USC 2683

CFR Citation:

40 CFR 745

Legal Deadline:

None

Abstract:

The Residential Lead-Based Paint Hazard Reduction Act of 1992 (title X) amended TSCA by adding a new title IV. TSCA section 403 requires EPA to promulgate regulations that identify lead-based paint hazards, lead-contaminated dust and lead-contaminated soil for the purposes of TSCA title IV as well as for the entire title X. EPA developed an interim guidance document in July 1994, to provide public and private decision-makers with guidance on identifying and prioritizing lead-based paint hazards for control. This interim guidance, which was subsequently published in 1995 (60 FR 47248, 9/11/95), will continue to serve as EPA's official policy until the final TSCA section 403 rule is promulgated.

Statement of Need:

Childhood lead poisoning is a pervasive problem in the United States, with almost a million young children having more than 10 ug/dl of lead in their blood, (Center for Disease Control's level of concern). Elevated blood-lead levels can lead to reduced intelligence and neurobehavioral problems in young children, as well as causing other adverse health effects in children and adults. Although there have been dramatic declines in blood-lead levels due to reductions of lead in paint, gasoline, and food sources, remaining paint in older houses remains the significant source of childhood lead poisoning. This regulation is a focal point of the Federal lead program and supports the implementation of regulations already promulgated (e.g., lead hazard disclosure in real estate transactions) as well as others under development (e.g., renovation and remodeling). By supporting the implementation of the national lead program, this rule would help prevent lead poisoning in children under the age of six.

Summary of Legal Basis:

This action is mandated by TSCA section 403.

Alternatives:

Alternatives were discussed in the proposed rule. Alternatives will be further considered as part of the proposed rule's comment review.

Anticipated Cost and Benefits:

The costs associated with the establishment of these levels were estimated in a draft economic impact analysis that was prepared for the proposed rule. Since benefits depend on private sector implementation of certain lead hazard abatement activities which are not mandated by any of these rules, benefits will be difficult to quantify. During its review of the NPRM under Executive Order 12866, OMB attributed the potential impact of all of the lead regulations to this rule and determined that this action should be classified as economically significant.

Risks:

This rule is aimed at reducing the prevalence and severity of lead poisoning, particularly in children.

Timetable:

Action	Date	FR Cite
NPRM	06/03/98	63 FR 30301
Notice - Comment Period Extended to 10/01/98	07/22/98	63 FR 39262
Notice - Comment Period Extended to 11/30/98	10/01/98	63 FR 52662
NPRM Correction	12/18/98	63 FR 70087
Notice Reopens Comment Period to 03/01/99	01/14/99	64 FR 2460
Final Action - Identification of Dangerous Levels of Lead	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State, Local, Tribal

Additional Information:

SAN No. 3243

Sectors Affected:

2332 Residential Building Construction; 235 Special Trade Contractors; 2352 Painting and Wall Covering Contractors; 23551 Carpentry Contractors; 23599 All Other Special Trade Contractors; 53111 Lessors of Residential Buildings and Dwellings; 531311 Residential Property Managers; 54135 Building Inspection Services; 54138 Testing Laboratories; 61151 Technical and Trade Schools; 92511 Administration of Housing Programs; 61171 Educational Support Services; 54161 Management Consulting Services

Agency Contact:

Lin Moos
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7404
Washington, DC 20460
Phone: 202 260-1866
Fax: 202 260-0770
Email: moos.lin@epa.gov

Dave Topping
Environmental Protection Agency
Office of Prevention, Pesticides and Toxic Substances
7404
Washington, DC 20460
Phone: 202 260-7737
Fax: 202 260-0770
Email: topping.dave@epa.gov

RIN: 2070–AC63

EPA

141. HAZARDOUS WASTE IDENTIFICATION RULE (HWIR): IDENTIFICATION AND LISTING OF HAZARDOUS WASTES

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 6912(a) RCRA sec 2002(a); 42 USC 6921 RCRA sec 3001; 42 USC 6922 RCRA sec 3002; 42 USC 6922 RCRA sec 3004; 42 USC 6926 RCRA sec 3006

CFR Citation:

40 CFR 261

Legal Deadline:

Other, Judicial, October 31, 1999, Reproposal.

Final, Judicial, April 30, 2001.

Abstract:

This action would amend regulations governing solid wastes that are designated as hazardous because they have been mixed with or derived from listed hazardous wastes. The Agency proposed to retain the mixture and derived-from rules promulgated under

the Resource Conservation and Recovery Act (RCRA). These rules are currently in effect on an emergency basis. The Agency proposed their retention.

The Agency also proposed two revisions to the mixture and derived-from rules. The first was an exemption for wastes and their residuals listed solely for the ignitability, corrosivity, and/or reactivity characteristics. The second, which EPA proposed in a separate notice, was a conditional exemption from the mixture and derived-from rules for mixed wastes (that is, wastes that are both hazardous and radioactive).

Because this action is deregulatory, it is not expected to have adverse impacts on small business. This action will be implemented by EPA and authorized States.

Statement of Need:

EPA has proposed to retain and amend the mixture rule and the derived-from rule in the hazardous waste identification regulations under the Resource Conservation and Recovery Act (RCRA). The mixture and derived-from rules ensure that hazardous wastes that are mixed with other wastes or that result from the treatment, storage or disposal of hazardous wastes do not escape regulation and thereby cause harm to human health and the environment. EPA proposed two revisions to the mixture and derived-from rules. The first is an exemption for mixtures and/or derivatives of wastes listed solely for the ignitability, corrosivity, and/or reactivity characteristics. The second is a conditional exemption from the mixture and derived-from rules for mixed wastes, (that is, wastes that are both hazardous and radioactive). These revisions would narrow the scope of the mixture and derived-from rules, tailoring the rules to more specifically match the risks posed by particular wastes.

Summary of Legal Basis:

This regulation will amend the mixture and derived-from rules, 40 CFR 261.3(a)(2)(iii) and (iv) and (c)(2)(i), and will create an exemption for low-risk waste. EPA is required to revise the mixture and derived-from rules under Public Law No. 102-389, 106 Stat. 1571. The mixture and derived-from rules and the exemption are exercises of EPA's authority under RCRA section 3001, 42 U.S.C. section 6921.

Alternatives:

EPA has considered a variety of alternatives for revising the mixture and derived-from rules, including developing a concentration-based generic exemption for low-risk listed waste and a specific exemption for wastes disposed of in a landfill. EPA will continue to explore these and other alternatives as appropriate.

Anticipated Cost and Benefits:

Revisions to the mixture and derived-from rules are expected to reduce the cost of shipping and disposing exempted wastes. Potential annual industry cost savings is estimated at $4.59 million, while annual reduction in truck shipment manifesting cost is estimated at $.45 million. After considering uncertainty factors (-15 percent to +30 percent), these two cost savings components represent a total annual cost savings estimate of $4.29 to $6.56 million per year.

Risks:

This rule would maintain current levels of risk protection.

Timetable:

Action	Date	FR Cite
NPRM	05/20/92	57 FR 21450
NPRM Withdrawn	10/30/92	57 FR 49280
NPRM Reproposal	12/21/95	60 FR 66344
NPRM Reproposal	11/19/99	64 FR 63381
Notice of Data Availability	07/18/00	65 FR 44491
Final Action	05/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 3328

Sectors Affected:

334 Computer and Electronic Product Manufacturing; 333 Machinery Manufacturing; 332 Fabricated Metal Product Manufacturing; 325 Chemical Manufacturing; 324 Petroleum and Coal Products Manufacturing; 331 Primary Metal Manufacturing; 335 Electrical Equipment, Appliance and Component Manufacturing; 336 Transportation Equipment Manufacturing

Agency Contact:

Tracy Atagi
Environmental Protection Agency
Solid Waste and Emergency Response
5304W
Washington, DC 20460
Phone: 703 308-8672
Fax: 703 308-0514
Email: atagi.tracy@epa.gov

Adam Klinger
Environmental Protection Agency
Solid Waste and Emergency Response
5304W
Washington, DC 20460
Phone: 703 308-3267
Fax: 703 308-0514
Email: klinger.adam@epa.gov

RIN: 2050–AE07

EPA

142. STORAGE, TREATMENT, TRANSPORTATION, AND DISPOSAL OF MIXED WASTE

Priority:

Other Significant

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 6905; 42 USC 6912(a); 42 USC 6921; 42 USC 6922; 42 USC 6924; 42 USC 6926; 42 USC 6927; 42 USC 6934

CFR Citation:

40 CFR 261.4; 40 CFR 262.34; 40 CFR 266

Legal Deadline:

NPRM, Judicial, October 31, 1999.

Final, Judicial, April 30, 2001.

Abstract:

The focus of the final rule is to provide flexibility under RCRA subtitle C to generators of eligible mixed waste. We intend to finalize a proposal for a conditional exemption from the definition of hazardous waste applicable to: low-level mixed waste (LLMW) for storage; and LLMW or Naturally Occurring and/or Accelerator-Produced Radioactive Material (NARM) for transportation and disposal. The rule is expected to reduce dual regulation for generators in the management and disposal of their wastes. This flexibility would enable generators of LLMW who are licensed by the Nuclear Regulatory Commission

(NRC) to claim an exemption for storing and treating these wastes in tanks or containers (using solidification, neutralization, or other stabilization processes) without a RCRA permit. This rule would also provide flexibility for the manifesting, transportation and disposal of eligible mixed waste. Waste meeting the conditions would be exempted from certain RCRA subtitle C hazardous waste requirements and managed as low-level radioactive waste in accordance with NRC regulations.

Statement of Need:

The final rulemaking is needed due to: industry concerns regarding the potential for duplication under EPA and NRC regulatory requirements; the lack of mixed waste treatment and disposal facilities nationwide; and follow through on comments relating to mixed waste management received from industry on the Hazardous Waste Identification Rule (HWIR) proposal of December 1995, and the mixed waste storage guidance of August 1995.

Summary of Legal Basis:

The final rulemaking is an outgrowth of the consent decree reached with the Edison Electric Institute, and other litigants and intervenors, in April 1997.

Alternatives:

EPA is considering a number of alternatives including: (1) use of LDR treatment standards for chemical constituents in conjunction with NRC disposal requirements for LLW; (2) applicability of HWIR exit concentration levels and associated requirements for chemical constituents; (3) a conditional exemption for stored mixed waste subject to NRC regulatory requirements; and (4) allowing decay-in-storage as provided by NRC for some mixed wastes to limit worker exposures to radionuclides.

Anticipated Cost and Benefits:

EPA anticipates that implementation of this rule could result in net cost savings of at least $1 to 3 million annually; unquantified cost savings from administrative and permitting burdens could be much higher. In addition, EPA anticipates possible risk reductions from reduced human exposure to radionuclides.

Risks:

The purpose of this rule is not risk reduction. The rule will maintain current level of protection as required by NRC for radionuclides under alternatives 1 and 3, and also provide protection for human health and the environment from chemical hazards. For alternative 2 the risk will be similar to HWIR risk benchmarks for carcinogens and non-carcinogens. For alternative 4, there would be a reduction in risk due to reduced exposure of workers to radionuclides mixed with hazardous wastes.

Timetable:

Action	Date	FR Cite
ANPRM	03/01/99	64 FR 10063
NPRM	11/19/99	64 FR 63463
Final Action	04/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, State, Tribal

Additional Information:

SAN No. 4017

SIC Codes: Nuclear Electric Power Generation (4911); Federal Facilities (9431) and (9511); Mixed Waste Treatment, Storage and Disposal Facilities (4953); Commercial Low Level Radioactive Waste Disposal Facilities (4953); Universities (8221); Medical Facilities (8071); Pharmaceutical Companies (2834); Research Laboratories (8731, 8734)

Sectors Affected:

3254 Pharmaceutical and Medicine Manufacturing; 562 Waste Management and Remediation Services; 562219 Other Nonhazardous Waste Treatment and Disposal; 61131 Colleges, Universities and Professional Schools; 6215 Medical and Diagnostic Laboratories; 622 Hospitals; 92 Public Administration; 8112 Electronic and Precision Equipment Repair and Maintenance

Agency Contact:

Nancy Hunt
Environmental Protection Agency
Solid Waste and Emergency Response
5303W
Washington, DC 20460
Phone: 703 308-8762
Fax: 703 308-8638
Email: hunt.nancy@epa.gov

Grace Ordaz
Environmental Protection Agency
Solid Waste and Emergency Response
5304W
Washington, DC 20460
Phone: 703 308-1130
Fax: 703 605-0744
Email: ordaz.grace@epa.gov

RIN: 2050–AE45

EPA

143. NATIONAL PRIMARY DRINKING WATER REGULATIONS: RADON

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal goverments.

Legal Authority:

42 USC 300(f) SDWA sec 1412

CFR Citation:

40 CFR 141; 40 CFR 142

Legal Deadline:

Other, Statutory, February 6, 1999, Publish radon health risk reduction and cost analysis.

NPRM, Statutory, August 6, 1999.

Final, Statutory, August 6, 2000.

Abstract:

EPA proposed new regulations for radon in drinking water which will provide States flexibility in how to manage the health risks from radon, in both drinking water and in indoor air. States would be able to focus their efforts on the highest radon risks to the public - in indoor air - while reducing the highest risks from radon in drinking water. Breathing indoor radon in homes is the primary public health risk from radon, contributing to about 20,000 lung cancer deaths each year in the United States, according to a landmark report this year by the National Academy of Sciences. That makes radon in indoor air the second leading cause of lung cancer in the United States. Based on a second NAS report, EPA estimates that radon in drinking

water causes about 168 cancer deaths per year, of which about 89 percent are lung cancer from breathing radon released from water. The remaining 11 percent of the risk is for stomach cancer from drinking radon-containing water.

The proposal is based on the unique framework outlined in the 1996 Safe Drinking Water Act (SDWA). The proposed new regulation will provide two options to States and water systems for reducing public health risks from radon. Under the first option, States can choose to develop enhanced state programs to address the health risks from indoor radon while water systems reduce radon levels in drinking water to the higher, alternative maximum contaminant level MCL of 4,000 pCi/L (picoCuries per liter, a standard unit of radiation) or lower, ensuring protection from the highest risks from radon in drinking water. EPA is encouraging the States to adopt this approach as the most cost-effective way to achieve the greatest radon risk reduction. If a State does not elect this option, the second option would require water systems in that State to either reduce radon in drinking water levels to the MCL of 300 pCi/L, or to develop a local indoor radon program and reduce levels in drinking water to 4000 pCi/L. Those systems initially at the MCL or lower will not need to treat their water for radon.

Statement of Need:

Radon in drinking water increases risk to public health, both from inhalation of radon discharged through normal water use, such as showering, and from ingestion of water.

Summary of Legal Basis:

Pursuant to the Safe Drinking Water Act, as amended in 1996 [sec. 1412 (b)(13)], EPA is required to: (1) withdraw the 1991 proposed radon in drinking water rule; (2) work with the National Academy of Sciences to conduct a risk assessment for radon in drinking water, and an assessment of the health risk reduction benefits associated with various mitigation methods of reducing radon in indoor air; (3) publish a radon health risk reduction and cost analysis for possible radon Maximum Contaminant Levels (MCLs) for public comment, by February 1999; (4) propose a Maximum Contaminant Level Goal (MCLG) and National Primary Drinking Water Regulation (NPDWR) for radon by August 1999; and (5) publish an MCLG and Final NPDWR for radon by August 2000.

In addition, if EPA promulgates an MCL more stringent than necessary to reduce the contribution to radon in indoor air from drinking water to a concentration that is equivalent to the national average concentration of radon in outdoor air, the Agency must establish an alternative MCL (AMCL). The AMCL is to be set at a level which would result in a contribution of radon from drinking water to radon levels in indoor air equivalent to the national average concentration of radon in outdoor air. If an alternative MCL is established, EPA must publish guidelines and criteria for States to develop multimedia radon mitigation programs. EPA shall approve State multimedia mitigation programs if they are expected to achieve equal or greater health risk reduction benefits than would be achieved through compliance with the MCL. If EPA approves a State multimedia mitigation program, public water supply systems within the State may comply with the AMCL. If a State does not have an approved multimedia mitigation program, any public water system may submit a program for approval by EPA according to the same criteria, conditions, and approval process that would apply to a State program. EPA shall evaluate multimedia mitigation programs every 5 years.

Alternatives:

EPA considered a range of MCL options for radon in drinking water in the Health Risk Reduction and Cost Analysis (HRRCA) (published in February 1999). The primary alternative is for a State or public water system to develop a multimedia mitigation program in order for it to comply with the AMCL. The National Academy of Sciences provided information on key factors (the water to air transfer factor and the national average outdoor radon level) that EPA will use in setting the AMCL.

Anticipated Cost and Benefits:

The total annual costs of compliance with the MCL of 300 pCi/l for radon in drinking water and the associated information collection and reporting requirements is estimated at $407 million. In complying with 300 pCi/l, an estimated 62.0 fatal and 0.2 nonfatal cancer cases are avoided each year. Because EPA expects that most States and systems will choose to comply with the alternative maximum contaminant level (AMCL) of 4,000 pCi/l and implement a Multi-Media Mitigation (MMM) program, EPA expects the total annual costs of compliance with the radon rule to be significantly less than $407 million. If most States and systems comply with the AMCL and implement an MMM program, the total annual costs of compliance are estimated at approximately $86 million. The quantifiable benefits of the health risk reduction are estimated to be $362 million for either implementation scenario. EPA expects compliance with the AMCL and implementation of an MMM program to achieve equal or greater risk reduction than is expected with strict compliance with the MCL.

Risks:

Radon is a naturally occurring volatile gas formed from the normal radioactive decay of uranium. It is colorless, odorless, tasteless, chemically inert, and radioactive. Exposure to radon and its progeny is believed to be associated with increased risks of several kinds of cancer. When radon or its progeny are inhaled, lung cancer accounts for most of the total incremental cancer risk. Ingestion of radon in water is suspected of being associated with increased risk of tumors of several internal organs, primarily the stomach. As required by the SDWA, as amended, EPA arranged for the National Academy of Sciences (NAS) to assess the health risks of radon in drinking water. The NAS released the pre-publication draft of a report on the Risks of Radon in Drinking Water, (NAS Report) in September 1998 and published the Report in July 1999. The analysis in this RIA uses information from the 1999 NAS Report. The NAS Report represents a comprehensive assessment of scientific data gathered to date on radon in drinking water. The report, in general, confirms earlier EPA scientific conclusions and analyses of radon in drinking water.

NAS estimated individual lifetime unit fatal cancer risks associated with exposure to radon from domestic water use for ingestion and inhalation pathways. The results show that inhalation of radon progeny accounts for most (approximately 88 percent) of the individual risk associated with domestic water use, with almost all of the remainder (11 percent) resulting from directly ingesting radon in drinking water. Inhalation of radon progeny is associated primarily with increased risk of lung cancer, while ingestion exposure is associated primarily with elevated risk of stomach cancer.

The NAS Report confirmed that indoor air contamination arising from soil gas

typically accounts for the bulk of total individual risk due to radon exposure. Usually, most radon gas enters indoor air by diffusion from soils through basement walls or foundation cracks or openings. Radon in domestic water generally contributes a small proportion of the total radon in indoor air. However, NAS recognized that radon in water is the largest source of cancer risk in drinking water compared to other regulated chemicals in water.

The NAS Report is one of the most important inputs used by EPA in its regulatory impact analysis. EPA has used the NAS's assessment of the cancer risks from radon in drinking water to estimate both the health risks posed by existing levels of radon in drinking water and also the cancer deaths prevented by reducing radon levels.

Timetable:

Action	Date	FR Cite
ANPRM	09/30/86	51 FR 34836
NPRM	07/18/91	56 FR 33050
Notice	02/26/99	64 FR 9560
NPRM	11/02/99	64 FR 59245
Final Action	06/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

SAN No. 2281

Sectors Affected:

22131 Water Supply and Irrigation Systems

Agency Contact:

Michael Osinski
Environmental Protection Agency
Water
4607
Washington, DC 20460
Phone: 202 260-6252
Fax: 202 260-3762
Email: osinski.michael@epa.gov

Sylvia Malm
Environmental Protection Agency
Water
4607
4607
Washington, DC 20460
Phone: 202 260-0417
Fax: 202 260-3762
Email: malm.sylvia@epa.gov

RIN: 2040–AA94

EPA

144. NATIONAL PRIMARY DRINKING WATER REGULATIONS: GROUND WATER RULE

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 300(f) SDWA sec 1412

CFR Citation:

40 CFR 141; 40 CFR 142

Legal Deadline:

Final, Statutory, May 31, 2002.

Abstract:

The Safe Drinking Water Act, as amended in 1996, directs EPA to promulgate regulations requiring disinfection, as necessary, for groundwater systems. The intention is to develop a protective public health approach which assures a baseline of protection for all consumers of ground water. It sets in place an increasingly targeted strategy to identify high risk or high priority systems that require greater scrutiny or further action. Development and implementation of the rule has involved local, tribal, State and Federal governments. The structure of the rule is a series of barriers to microbial contamination. The multiple-barrier approach relies upon five major components: (1) periodic onsite inspections of ground water systems requiring the evaluation of eight key areas and the identification of significant deficiencies; (2) source water monitoring for systems drawing from sensitive aquifers without treatment or with other indications of risk; (3) a requirement for correction of significant deficiencies; (4) a requirement for treatment where contamination or significant deficiencies are not or cannot be corrected, and alternative sources of drinking water are not available; and, (5) compliance monitoring to insure disinfection treatment is reliable and effective. EPA believes that the combination of these elements strikes an appropriate regulatory balance which tailors the intensity or burden of protective measures and follow-up action to the risk being addressed.

Statement of Need:

Public water systems (PWSs) that use groundwater as their sole source of water, as opposed to surface water PWSs, are not federally regulated as to treatment for microorganisms. There is data that indicates that a number of groundwater PWSs are contaminated with microorganisms of fecal origin that can and have caused illness.

Summary of Legal Basis:

Section 1412(b)(8) of the Safe Drinking Water Act requires that EPA develop regulations specifying the use of disinfectants for groundwater systems as necessary and ''...(as part of the regulations) promulgate criteria...to determine whether disinfection shall be required as a treatment technique for any public water system served by groundwater.''

Alternatives:

EPA considered four regulatory alternatives in the development of the GWR proposal: the proposed regulatory alternative (multibarrier option); the sanitary survey option; the sanitary survey and triggered monitoring option; and the across-the-board disinfection option. All options include the sanitary survey provision. The sanitary survey option would require the primary agency to perform surveys every three to five years, depending on the type of system. If any significant deficiency is identified, a system is required to correct it. The sanitary survey and triggered monitoring option adds a source water fecal indicator monitoring requirement triggered by a total coliform positive sample in the distribution system. The multibarrier option, which was proposed by EPA, adds a hydrogeologic sensitivity assessment to these elements which, if a system is found to be sensitive,

results in a routine source water fecal indicator monitoring requirement. The multibarrier option and the sanitary survey and triggered monitoring options are both a targeted regulatory approach designed to identify wells that are fecally contaminated or are at a high risk for contamination. The across-the-board disinfection option would require all systems to install treatment instead of trying to identify only the high risk systems; therefore, it has no requirement for sensitivity assessment or microbial monitoring.

Anticipated Cost and Benefits:

EPA estimates the cost of the proposed GWR will be $183 million dollars per year (using a 3 percent discount rate). More than half of the estimated costs are for corrective actions which systems will be required to take to fix or prevent fecal contamination. The remainder of the costs are due to increased scope and frequency of sanitary surveys, hydrogeologic sensitivity assessments and source water monitoring. System costs are expected to be $162 million per year for implementation of the GWR. States are expected to incur costs of $21 million per year. Cost estimates do not include land acquisition, public notification or the potential cost of illness due to exposure to disinfection byproducts. The total estimated value of these benefits is $205 million per year, $139 million from avoided illness and $66 million from avoided deaths. These benefits are monetized based on a cost of illness and a value of statistical life. These estimates do not include pain and suffering associated with viral and bacterial illness, avoided outbreak response costs (such as the costs of providing public health warnings and boiling drinking water), and possibly the avoided costs of averting behavior and reduced uncertainty about drinking water quality.

Risks:

EPA estimates that currently over 200,000 illnesses and 18 deaths occur each year due to viral and bacterial contamination of public ground water systems. Children, the elderly and the immunocompromised are particularly sensitive to the waterborne pathogens and account for between 20 and 30 percent of the illnesses and deaths. The proposed GWR is expected to reduce the total number of illness by 115,000 and the total number of deaths by 11 each year. The GWR in conjunction with the Surface Water Treatment Rule (SWTR), Total Coliform Rule (TCR) the Interim Enhanced Surface Water Treatment Rule (IESWTR), the Filter Backwash Rule (FBR) and the Long Term Enhanced Surface Water Treatment Rules (LT1ESWTR & LT2ESWTR) will provide protections to the consumers of public water supply systems from waterborne pathogens.

Timetable:

Action	Date	FR Cite
NPRM	05/10/00	65 FR 30194
Final Action	06/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

SAN No. 2340

Statutory deadline for final: After August 6, 1999 but before May 31, 2002.

Sectors Affected:

22131 Water Supply and Irrigation Systems

Agency Contact:

Eric Burneson
Environmental Protection Agency
Water
4607
Washington, DC 20460
Phone: 202 260-1445
Fax: 202 401-6135
Email: burneson.eric@epa.gov

Tracy Bone
Environmental Protection Agency
Water
4607
Washington, DC 20460
Phone: 202 260-2954
Fax: 202 401-6135
Email: bone.tracy@epa.gov

RIN: 2040–AA97

EPA

145. NATIONAL PRIMARY DRINKING WATER REGULATIONS: ARSENIC AND CLARIFICATIONS TO COMPLIANCE AND NEW SOURCE CONTAMINANT MONITORING

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

This action may affect State, local or tribal goverments and the private sector.

Legal Authority:

42 USC 300(f) SDWA sec 1412

CFR Citation:

40 CFR 141(Revision); 40 CFR 142 (Revision)

Legal Deadline:

NPRM, Statutory, January 1, 2000.

Final, Statutory, January 1, 2001.

Abstract:

The Safe Drinking Water Act (SDWA) Amendments of 1996 require EPA to develop a plan and research health risks of low levels of arsenic. In addition, EPA must propose a revised drinking water regulation for arsenic by January 1, 2000, and issue a final rule by January 1, 2001. Currently the drinking water standard for arsenic is 0.05 mg/L or 50 ug/L. A March 1999 National Academy of Sciences report urged EPA to lower the drinking water standard, because inorganic arsenic causes bladder, lung and other internal cancers in humans. The report recommended additional studies to characterize health effects at low doses for cancers, cardiovascular disease, diabetes, reproductive effects, and children.

EPA generally sets the enforceable maximum contaminant level (MCL) as close to the health-based maximum contaminant level goal (MCLG) as feasible, considering treatment efficacy and costs, but may set an alternative level depending on the balance of costs and benefits in certain cases. EPA must list affordable technologies or treatment techniques that achieve compliance with the MCL for three categories of small systems considering the quality of the source water. Furthermore, alternatives to central treatment, such as point-of-use and point-of-entry devices, can be considered for small systems that maintain control over operation and maintenance.

In addition, in this final rule, EPA intends to clarify compliance monitoring requirements for new public water systems and new water sources. These clarifications would apply to inorganic, volatile organic, and synthetic organic contaminants.

Statement of Need:

The U.S. Public Health Service first established a drinking water standard for arsenic at 50 ug/L in 1942. The Safe Drinking Water Act of 1974 (SDWA) which amended the Public Health Service Act specified that EPA set drinking water standards. In 1975 EPA issued a National Interim Primary Drinking Water Regulation for arsenic at 50 ug/L, noting no illness. After EPA's risk assessment approach calculated a much lower arsenic criteria to protect humans from skin cancer for surface water quality criteria under the Clean Water Act, the drinking water program retained its 50 ug/L standard. EPA did not revise the standard as required by 1986 amendments to SDWA, based on the need to better characterize health effects and assess arsenic removal technologies. At that time, EPA's analysis estimated it would cost $2.1 billion a year to comply with a standard protective of health (skin cancer). The 1996 amendments to the Safe Drinking Water Act require EPA to determine whether the costs of regulation would justify the benefits, including consideration of nonquantifiable benefits. In addition, EPA must determine the incremental costs and benefits of alternatives considered that do not include what would occur from compliance with other proposed or final regulations. If the costs do not justify the benefits, the Administrator may choose to raise the MCL to a level still protective of health at which costs do justify the benefits. As noted in ι17 above, the 1999 report issued by the National Academy of Sciences definitely implicated inorganic arsenic's effects on bladder, lung, and skin cancer. Based on existing data, EPA is urged to lower the drinking water standard as soon as possible.

Summary of Legal Basis:

1412(b)(12) CERTAIN CONTAMINANTS.

(A) ARSENIC.: (i) SCHEDULE AND STANDARD.— Notwithstanding the deadlines set forth in paragraph (1), the Administrator shall promulgate a national primary drinking water regulation for arsenic pursuant to this subsection, in accordance with the schedule established by this paragraph.

(ii) STUDY PLAN.— Not later than 180 days after the date of enactment of this paragraph, the Administrator shall develop a comprehensive plan for study in support of drinking water rulemaking to reduce the uncertainty in assessing health risks associated with exposure to low levels of arsenic. In conducting such study, the Administrator shall consult with the National Academy of Sciences, other Federal agencies, and interested public and private entities.

(iii) COOPERATIVE AGREEMENTS.— In carrying out the study plan, the Administrator may enter into cooperative agreements with other Federal agencies, State and local governments, and other interested public and private entities.

(iv) PROPOSED REGULATIONS.— The Administrator shall propose a national primary drinking water regulation for arsenic not later than January 1, 2000.

(v) FINAL REGULATIONS.— Not later than January 1, 2001, after notice and opportunity for public comment, the Administrator shall promulgate a national primary drinking water regulation for arsenic.

(vi) AUTHORIZATION.— There are authorized to be appropriated $2.5 million for each of fiscal years 1997 through 2000 for the studies required by this paragraph.

Also see: 1412(b)(4)(E)(ii) for listing small system technologies 1412(b)(4)(C) for requiring analysis of whether costs justify benefits 1412(b)(3)(C)(i) for other requirements for the cost-benefit analyses 1412(b)(15) for small system variance technologies, if, considering the source water, no treatment technology is listed.

Alternatives:

EPA proposed an MCL of 5 ug/L for arsenic and requested comment on MCL options of 3, 10, and 20 ug/L. EPA provided benefit analyses of each of these alternatives, measured as reducing drinking water arsenic from the current standard of 50 ug/L. This proposal lists affordable technologies for small systems, as required by the 1996 amendments to the statute. Because EPA identified affordable compliance technologies for all small system sizes, EPA did not list small system variance technologies.

Anticipated Cost and Benefits:

Estimated Costs:

Over 98 percent of the cost of the arsenic rule comes from adding treatment equipment, chemicals, and oversight of the new treatment. At the proposed level of 5 ug/L for arsenic in drinking water: the total annualized costs of treatment, monitoring, reporting, recordkeeping, and administration for the 6,600 CWSs needing to reduce arsenic will be $379 million a year at 3 percent discount rates and $445 million a year at 7 percent discount rates; State and Federal administrative costs are projected to be $3 million per year (at a 3 percent discount rate) to $5 million per year (at a 7 percent discount rate).

At the regulatory option of 3 ug/L, total annualized costs of treatment, monitoring, reporting, recordkeeping, and administration will be $645 million a year at 3 percent discount rates and $756 million a year at 7 percent discount rates. At the regulatory option of 10 ug/L, total costs of treatment, monitoring, reporting, recordkeeping, and administration will be $166 million a year at 3 percent discount rates and $195 million a year at 7 percent discount rates. At the regulatory option of 20 ug/L, total costs of treatment, monitoring, reporting, recordkeeping, and administration will be $65 million a year at 3 percent discount rates and $77 million a year at 7 percent discount rates.

Estimated Benefits:

Reducing arsenic from 50 ug/L to 5 ug/L - protects an additional 22.5 million Americans and will prevent about 20 cases of bladder cancer per year and approximately 5 bladder cancer deaths per year.

At a regulatory option of 3 ug/L, reducing arsenic from 50 ug/L to 3 ug/L - protects an additional 35.7 million Americans and will prevent about 25 cases of bladder cancer and approximately 7 bladder cancer deaths per year.

At a regulatory option of 10 ug/L, reducing arsenic from 50 ug/L to 10 ug/L - protects an additional 10.7 million Americans and will prevent about 13 cases of bladder cancer and approximately 3 bladder cancer deaths per year.

Under a regulatory option of 20 ug/L, reducing arsenic from 50 ug/L to 20 ug/L - protects an additional 4.4 million Americans and will prevent about 7 cases of bladder cancer and approximately 2 bladder cancer deaths per year.

EPA expects that arsenic-related lung cancers (that could number as many as two to five times the number of bladder cancers) and cardiovascular diseases

will be reduced with a lower standard as well.

The estimated values of the benefits of this rule range from as high as $90 million for bladder cancer to $384 million for lung cancer.

Risks:

According to the report issued by the National Academy of Sciences, the risk of male bladder cancer at the current standard is 1 to 1.5 additional cancers per thousand people, or 1-1.5 x 10-3, based on a linear approach.

Timetable:

Action	Date	FR Cite
Plan Arsenic Research Topics for Funding	12/24/96	61 FR 67800
NPRM	06/22/00	65 FR 38888
Final Action	06/00/01	

Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses, Organizations, Governmental Jurisdictions

Government Levels Affected:

Federal, State, Local, Tribal

Federalism:

This action may have federalism implications as defined in EO 13132.

Additional Information:

SAN No. 2807

Sectors Affected:

22131 Water Supply and Irrigation Systems

Agency Contact:

Irene Dooley
Environmental Protection Agency
Water
4607
Washington, DC 20460
Phone: 202 260-9531
Fax: 202 260-3762
Email: dooley.irene@epa.gov

RIN: 2040–AB75

EPA

146. ● TRI; LOWERING OF EPCRA SECTION 313 REPORTING THRESHOLDS FOR LEAD AND LEAD COMPOUNDS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

42 USC 11001 et seq

CFR Citation:

40 CFR 372

Legal Deadline:

None

Abstract:

The Toxics Release Inventory (TRI) currently requires reporting from facilities which manufacture or process at least 25,000 pounds of a listed chemical, or otherwise use 10,000 pounds of a listed chemical. These thresholds were initially established under the Emergency Planning and community Right-To-Know Act (EPCRA) section 313(f)(1). Section 313(f)(2) of EPCRA gives the Administrator the power to establish a threshold amount for a toxic chemical different from the amount established by paragraph (1), and that such altered thresholds may be based on classes of chemicals. EPA is considering lowering the thresholds for certain persistent bioaccumulative toxic (PBT) chemicals and has issued a proposed rule that sets out the criteria EPA intends to use for determining if a chemical is persistent and bioaccumulative under EPCRA section 313. EPA is currently conducting analysis to determine if lead and lead compounds meet the proposed criteria for persistence and bioaccumulation and whether the EPCRA section 313 reporting thresholds should be lowered. EPA is also evaluating the environmental fate of lead.

Statement of Need:

TRI is the most complete and accessible source of information for the public on toxic chemical releases in communities across the United States. The intention of Congress was for TRI, and indeed all of EPCRA, to provide information to local communities. Communities need this information to better understand the nature of the releases at the local level. The intent of TRI has been to share information on releases with local communities to help in their assessments of the risks. This basic local empowerment is the cornerstone of the right-to-know program. Yet because of the current reporting thresholds, TRI does not collect release and transfer data on small quantities of lead and lead compounds that may persist and bioaccumulate in the environment. Even small releases of lead and lead compounds can have significant impacts on human health and the environment. Congress gave EPA the authority to adjust reporting thresholds, because it recognized that this might be necessary in order to address the American public's right to know what is happening to the environment near their homes, schools, and businesses.

Summary of Legal Basis:

42 USC 11023(f)(2); 42 USC 11048; EPCRA S313; EPCRA S328.

Alternatives:

EPA recognizes the reporting burden inherent in TRI, and is continuing to take every reasonable opportunity to minimize this burden while ensuring the public's right to know. As such, all available alternatives will be identified and evaluated.

Anticipated Cost and Benefits:

EPA has proposed to lower the EPCRA section 313 reporting thresholds for lead and lead compounds to 10 pounds. Under this proposal the estimated aggregate industry cost in the first year would be $116 million and in subsequent years would be $60 million. The information reported in TRI increases the knowledge levels of lead and lead compounds released to the environment and pathways to exposure, improving scientific understanding of the health and environmental risks of toxic chemicals; allows the public to make informed decisions on where to work and live; enhances the ability of corporate lenders and purchasers to more accurately gauge a facility's potential liability; and assists Federal, State, and local authorities in making better decisions on acceptable levels of toxics in communities.

Risks:

Currently communities do not have access to TRI data on lead and lead compounds that, although released in relatively small quantities, pose a potential risk to human health and the environment because they persist and bioaccumulate. By lowering the reporting thresholds for lead and lead compounds the public will be able to determine if these chemicals are being released into their communities and whether any action should be taken to reduce potential risks.

Timetable:

Action	Date	FR Cite
NPRM	08/03/99	64 FR 42222
Notice Extension of Comment Period to 11/01/99	09/21/99	64 FR 51093
Notice Extension of Comment Period to 12/16/99	10/29/99	64 FR 58370
Final Action	10/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, State

Additional Information:

SAN No. 4259

Fomerly listed as RIN 2070-AD38.

By statute and regulation, this rule will affect SIC codes 20-39, 10 (except SIC codes 1011, 1081, 1094), 12 (except SIC code 1241), 4911, 4931, 4939, 4953, 5169, 5171, and 7389.

Agency Contact:

Maria Doa
Environmental Protection Agency
Office of Environmental Information
2844
Washington, DC 20460
Phone: 202 260-9592
Fax: 202 401-8142
Email: doa.maria@epa.gov

Daniel R. Bushman
Environmental Protection Agency
Office of Environmental Information
2844
Washington, DC 20460
Phone: 202 260-3882
Fax: 202 401-8142
Email: bushman.daniel@epa.gov

RIN: 2025–AA05

BILLING CODE 6560–50–S

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION (EEOC)

Statement of Regulatory and Deregulatory Priorities

The Equal Employment Opportunity Commission (EEOC) enforces six statutes prohibiting discrimination in employment. Title VII of the Civil Rights Act of 1964, as amended, prohibits employment discrimination on the basis of race, color, sex, religion, or national origin. The Equal Pay Act of 1963, as amended, prohibits the payment of different wages to women and men working in the same establishment, performing equal work that requires equal skill, effort, and responsibility under similar working conditions, unless the pay differential is based on a factor(s) other than sex. The Age Discrimination in Employment Act of 1967 (ADEA), as amended, prohibits employment discrimination on the basis of age against people age 40 and older. Title I of the Americans with Disabilities Act of 1990 (ADA), as amended, prohibits employment discrimination against qualified individuals with disabilities. Sections 501 and 505 of the Rehabilitation Act of 1973, as amended, prohibit Federal agencies from discriminating in employment against qualified individuals with disabilities and require agencies to accommodate the special needs of persons with disabilities. The Government Employee Rights Act of 1991 extends protections against employment discrimination to certain employees who were not previously covered.

The mission of the Agency is to ensure equality of opportunity by vigorously enforcing Federal legislation prohibiting discrimination in employment. Enforcement is accomplished through investigation, conciliation, alternative methods of dispute resolution, litigation, coordination, and regulation, as well as by education, policy research, and technical assistance. In pursuing its mission of eradicating discrimination in the workplace, the Commission intends that its enforcement be certain and predictable and that its remedies be preventive and remedial in scope.

One important step toward these ends is to make sure that employees, employers, and union representatives understand their rights and obligations under the Federal laws prohibiting employment discrimination. In accordance with the President's national regulatory principles, EEOC develops regulations necessary to inform employees and employers of their rights and obligations under the statutes it enforces. EEOC further educates the public on an ongoing and proactive basis through interpretive guidelines, policy documents, management directives, and other public guidance programs.

EEOC is currently considering two significant actions of a regulatory nature. Both have been published for public comment.

One of the significant actions the Commission proposes is to issue legislative regulations to provide detailed guidance for employers and employees on tender back of consideration paid for a waiver of rights and claims under the ADEA. These issues were addressed by the United States Supreme Court's decision in Oubre v. Entergy Operations, Inc., 522 U.S. 422 (1998). The proposed rule is titled Waivers of Rights and Claims: Tender Back of Consideration and was published for public comment (NPRM) on April 23, 1999, 64 FR 19952. The Commission is assessing all comments received in response to this NPRM.

The second significant action of a regulatory nature that the Commission proposes is amendment of its regulation governing Federal sector equal employment opportunity, 29 CFR 1614.203, to reflect the 1992 amendment of section 501 of the Rehabilitation Act of 1973. Congress amended section 501 to state that the nondiscrimination standards of title I of the Americans with Disabilities Act apply to complaints under section 501 of the Rehabilitation Act. The proposed rule is titled Federal Sector Equal Employment Opportunity and was published for public comment (NPRM) on March 1, 2000, 65 FR 11019.

(Consistent with section 4(c) of Executive Order 12866, this statement was reviewed and approved by the Chairwoman of the Agency. The statement has not been reviewed or approved by the other members of the Commission).

EEOC

FINAL RULE STAGE

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147. FEDERAL SECTOR EQUAL EMPLOYMENT OPPORTUNITY

Priority:

Other Significant

Legal Authority:

PL 102-569, The Rehabilitation Act Amendments of 1992; 42 USC 2000e-16; 29 USC 794a

CFR Citation:

29 CFR 1614

Legal Deadline:

None

Abstract:

The Commission proposes to change its Federal sector equal employment opportunity regulations to implement the Rehabilitation Act Amendments of 1992. The 1992 amendments provide that the standards used to determine if title I of the Americans with Disabilities Act has been violated will apply to complaints of nonaffirmative action employment discrimination under section 501 of the Rehabilitation Act.

Statement of Need:

The Commission promulgated its latest regulation under section 501 of the Rehabilitation Act in April 1992, several months before Congress enacted the 1992 Rehabilitation Act Amendments. The Commission is thus proposing to amend its section 501 regulation, found at 29 CFR 1614.203, to implement the Rehabilitation Act Amendments.

Summary of Legal Basis:

Pursuant to sections 501 and 505 of the Rehabilitation Act, the Commission is authorized to issue such regulations as it deems necessary to carry out its responsibilities under the Act. The proposed regulatory revisions are not required by statute or court order.

Alternatives:

The Commission has consulted with stakeholders and has considered their suggested alternatives in developing this regulatory proposal. The Commission will consider all alternatives offered by public commenters.

Anticipated Cost and Benefits:

The proposed regulatory changes will enhance enforcement of the statutory requirements. Federal agencies and individuals will have a clearer understanding of their respective obligations and rights under the Rehabilitation Act. It is not anticipated that this proposal will result in increased costs.

Risks:

The proposed regulatory changes will lessen the risk of noncompliance with

statutory requirements by identifying and providing detailed guidance on the appropriate legal standards governing Federal sector claims of nonaffirmative action employment discrimination under section 501 of the Rehabilitation Act. This proposal does not address risks to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	03/01/00	65 FR 11019
NPRM Comment Period End	05/01/00	
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Federal

Agency Contact:

Carol Miaskoff
Assistant Legal Counsel, Office of Legal Counsel
Equal Employment Opportunity Commission
Room 6037
1801 L Street NW
Washington, DC 20507
Phone: 202 663-4689
TDD Phone: 202 663-7026
Fax: 202 663-4639

RIN: 3046–AA57

EEOC

148. WAIVERS OF RIGHTS AND CLAIMS: TENDER BACK OF CONSIDERATION

Priority:

Other Significant

Legal Authority:

5 USC 522; 29 USC 628; 42 USC 2000e; 42 USC 12101; 29 USC 206(d)

CFR Citation:

29 CFR 1625

Legal Deadline:

None

Abstract:

Following the United States Supreme Court's decision in Oubre v. Entergy Operations, Inc., 522 U.S. 422 (1998), the Commission has developed proposed regulatory guidance on the status of consideration paid for a waiver of rights and claims under the ADEA.

Statement of Need:

The Equal Employment Opportunity Commission (EEOC or Commission) is proposing to adopt legislative regulations addressing issues relating to the ''tender back of consideration'' in connection with waivers of rights and claims under the Age Discrimination in Employment Act of 1967 (ADEA). This issue was addressed by the United States Supreme Court in Oubre v. Entergy Operations, Inc., 522 U.S. 422 (1998). In that decision, the Supreme Court held that an individual was not required to return (tender back) consideration (such as improved severance benefits, extra money, or early retirement) for a waiver in order to allege a violation of the ADEA. Prior to the Supreme Court's decision in Oubre, the Federal courts of appeals were split on the issue of whether an individual who signed a waiver agreement was required to tender back any consideration paid by the employer in order to bring a claim under the ADEA. The Commission's proposed legislative rule would provide detailed regulatory guidance to the public on the tender back issue addressed by the Supreme Court's Oubre decision.

The ADEA was amended by title II of the Older Worker Benefits Protection Act of 1990 (OWBPA) to regulate the use of waivers for employees 40 years of age or older. Title II of OWBPA sets forth the statutory requirements for a valid waiver of rights under the ADEA. The Commission conducted a negotiated rulemaking in 1995 and 1996 on ADEA waivers under OWBPA. The Rulemaking Committee considered, but agreed not to resolve, the tender back issue, and it was not included in the regulatory language recommended by the Committee to the Commission. EEOC promulgated a final regulation on ADEA waivers at 29 CFR 1625.22 on June 5, 1998, 63 FR 30624. The preamble to the final regulation confirmed that the issues raised in the Supreme Court's Oubre decision would not be addressed in that regulation, but that the tender back issue would be covered in other EEOC guidance.

Since the enactment of OWBPA, employer and employee representatives have expressed continuing interest in receiving guidance on the issue of waiver agreements. The use of waiver agreements in the workplace is an increasingly common practice, particularly in connection with layoffs and reductions-in-force. The Supreme Court recognized in Oubre that requiring tender back of consideration, as a condition of bringing an ADEA suit, could frustrate the purposes of the statute and lead to evasion of OWBPA's waiver requirements. Because of the importance of the tender back issue to both employers and employees, the Commission believes that the public would benefit from regulatory guidance in this area.

Summary of Legal Basis:

Section 9 of ADEA authorizes the Commission to issue such rules and regulations as it may consider necessary or appropriate for carrying out the Act. This regulatory proposal is not required by statute or court order.

Alternatives:

The Commission considers all alternatives offered by public commenters.

Anticipated Cost and Benefits:

Providing a clear outline of what is and is not permissible concerning issues raised by the Supreme Court's Oubre decision will reduce employment disputes and save both employers and employees time and unnecessary costs. In addition, regulatory guidance on the issue of waiver agreements should result in increased voluntary resolution of potential employment disputes, and thereby reduce the likelihood of protracted and costly litigation. Finally, when necessary, regulatory guidance on tender back of consideration paid under waiver agreements will ensure that employees are able to challenge the validity of such agreements. It is not anticipated that any costs will arise from issuing the proposed regulatory guidance.

Risks:

Regulatory guidance on tender back issues will lessen the risk that employees will be forestalled from challenging the validity of waivers under the laws enforced by EEOC in the event that they are unable to tender back consideration. The Commission has a substantial interest in addressing this risk. The right of individual employees to challenge waiver agreements is essential to implement the strong public interest in eradicating discrimination in the workplace and is also a vital part of the statutory enforcement scheme of the ADEA, as well as the other laws enforced by the Commission. The proposed regulation does not address risks to public health, safety, or the environment.

Timetable:

Action	Date	FR Cite
NPRM	04/23/99	64 FR 19952
NPRM Comment Period End	06/22/99	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Local, Federal

Agency Contact:

Carol Miaskoff
Assistant Legal Counsel, Office of Legal Counsel
Equal Employment Opportunity Commission
Room 6037
1801 L Street NW
Washington, DC 20507
Phone: 202 663-4689
TDD Phone: 202 663-7026
Fax: 202 663-4639

RIN: 3046–AA68

BILLING CODE 6570–01–S

GENERAL SERVICES ADMINISTRATION (GSA)

Statement of Regulatory and Deregulatory Priorities

The General Services Administration (GSA) establishes Governmentwide policy for acquisition, management, utilization and disposal of real property and personal property, and administrative services. More specifically, these policies address travel and transportation, the construction and operation of buildings, information technology, the use of advisory committees, and developing electronic Government.

GSA's fiscal year 2001 regulatory priorities are to complete production of the Federal Management Regulation (FMR) and to finish rewriting the Federal Travel Regulation. The FMR is being written to replace the Federal Property Management Regulations (FPMR); as each part of the FMR is published, the corresponding parts of the FPMR will be removed.

The new FTR and FMR are intended to make GSA's regulations consistent and sensible and to limit the regulatory burden on Government officials and the public. They are being written in a question and answer format to make them easier to read and understand, and non-regulatory guidance is being moved into other, less formal publications.

BILLING CODE 6820–34–S

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

Statement of Regulatory Priorities

The National Aeronautics and Space Administration (NASA) was established by the National Aeronautics and Space Act of 1958 (the Act), 42 United States Code (U.S.C.) 2451 *et seq.*, which laid the foundation for NASA's mission. The Act authorizes NASA, among other things, to conduct space activities devoted to peaceful purposes for the benefit of humankind; to preserve the leadership of the United States in aeronautics and space science and technology; and to expand knowledge of the Earth and space. To carry out this mission, NASA is authorized to conduct research for the solution of problems of flight within and outside the Earth's atmosphere; to develop, construct, test, and operate aeronautical and space vehicles for research purposes; to operate space transportation systems, including the Space Shuttle and the International Space Station; and to perform such other activities as may be required for the exploration of space. NASA conducts activities required for the exploration of space with human tended, robotic, and expendable vehicles and arranges for the most effective utilization of the scientific and engineering resources of the United States with other nations engaged in aeronautical and space activities for peaceful purposes.

NASA's mission, as documented in its 1998 Strategic Plan (with 1999 Interim Adjustments), is to advance and communicate scientific knowledge and understanding of the Earth, the solar system, and the universe; to advance human exploration, use, and development of space; and to research, develop, verify, and transfer advanced aeronautics and space technologies.

The following are narrative descriptions of the most important regulations being planned for publication in the **Federal Register** during fiscal year (FY) 2001.

The Federal Acquisition Regulation (FAR), 48 CFR chapter 1, contains procurement regulations that apply to NASA and other Federal agencies. NASA implements and supplements FAR requirements through the NASA FAR Supplement (NFS), 48 CFR chapter 18. Major revisions are not expected in FY 2001, except to conform to FAR changes that are currently being promulgated in part 12, Acquisition of Commercial Items, and part 45, Government Property.

In a continuing effort to keep the NFS current with NASA initiatives and Federal procurement policy, minor revisions to the NFS will be published. For instance, NASA has promulgated an interim rule on a risk-centered approach to acquisition that will affect acquisition planning, contract structure, contractor surveillance, and other contract management areas, which will result in NFS revisions.

To reduce the time and cost spent by the Agency and by our science and industry partners in the procurement of basic and applied research, NASA is focusing on streamlining our processes. To go forward in this effort, regulations governing Grant and Cooperative Agreements at 14 CFR parts 1260, 1273, and 1274, were rewritten and published as a proposed rule. Numerous comments were received and are being addressed in the formulation of the final rule.

NASA is continuing consideration of revisions to the cross-waiver of liability regulation at 14 CFR part 1266. Specifically, NASA is considering implementation of the cross-waiver of liability provision of the intergovernmental agreement of the International Space Station and refinement and clarification of contractual cross-waivers in NASA agreements involving launch services.

NASA is also continuing consideration of a new regulation that would clarify and provide procedures for exercising its claims authority under 42 U.S.C. 2473 (c)(13), section 203 (c)(13) of the Act, as amended, especially as applied to Agency functions such as launches of NASA missions.

NASA is amending 14 CFR part 1214 to add a new subpart 1214.4 entitled International Space Station Crew. This subpart will implement certain provisions of the International Space Station (ISS) Intergovernmental Agreement regarding ISS crew members' observance of an ISS Code of Conduct.

NASA

FINAL RULE STAGE

149. ● CODE OF CONDUCT FOR INTERNATIONAL SPACE STATION CREW

Priority:

Other Significant

Legal Authority:

42 USC 2455, 2473, 2475; 18 USC 799

CFR Citation:

14 CFR 1214, subpart 1214.4

Legal Deadline:

None

Abstract:

NASA is amending the title of 14 CFR and adding subpart 1214.4 to implement certain provisions of the International Space Station Intergovernmental Agreement regarding crew members' observance of a Code of Conduct.

Statement of Need:

To establish and implement a Code of Conduct for crew members of the International Space Station (ISS).

Summary of Legal Basis:

Required by the provisions of the ISS Intergovernmental Agreement (IGA), entered into pursuant to 42 U.S.C. 2455, 2473, and 2475.

Alternatives:

None or Not Applicable (N/A).

Anticipated Cost and Benefits:

Costs-N/A; benefits-compliance with our international agreement, the IGA.

Risks:

Violation of the IGA.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

John F. Hall Jr.
Senior Counsel (Commercial International)
National Aeronautics and Space Administration
Office of the General Counsel, Code GS
NASA Headquarters
Washington, DC 20546
Phone: 202 358-2432
Fax: 202 358-4355
Email: jhall@hq.nasa.gov

RIN: 2700–AC40

BILLING CODE 7510–01–S

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION (NARA)

Statement of Regulatory Priorities

The National Archives and Records Administration (NARA) issues regulations directed to other Federal agencies and to the public. Records management regulations directed to Federal agencies concern proper management and disposition of Federal records. Through the Information Security Oversight Office (ISOO), NARA also issues Governmentwide regulations concerning information security classification and declassification programs. NARA regulations directed to the public address access to and use of our historically valuable holdings, including archives, donated historical materials, Nixon Presidential materials, and Presidential records. NARA also issues regulations relating to the National Historical Publications and Records Commission (NHPRC) grant programs.

NARA's regulatory priorities for fiscal year 2001 are: (1) developing regulations relating to storage standards for archival records; (2) reviewing 36 CFR part 1230, Micrographic Records Management, to update industry standards and to consider expanding the part to address other imaging technologies; (3) revising regulations on transfer of electronic records to the National Archives of the United States to allow additional transfer media; and (4) updating and streamlining NARA regulations relating to the National Historical Publications and Records Commission grant program.

BILLING CODE 7515–01–S

OFFICE OF PERSONNEL MANAGEMENT (OPM)

Statement of Regulatory Priorities

The Office of Personnel Management's (OPM) regulatory priorities for the coming year will continue to focus on human resource management improvements that will enable the Federal Government to recruit, manage, and retain the high quality, diverse workforce needed by agencies to deliver their respective missions to the American public.

An unqualified success story of the Clinton Administration has been the historic transformation of our Federal workforce; a workforce that is the smallest it has been since the Eisenhower Administration as a result of needed Government workforce restructuring, yet one that operates with increased efficiency. It is managed with concern for balancing the work and family needs of its employees with a renewed commitment for getting results for the American people. It is focused on innovation and aggressively seeking ways to incorporate e-learning into the training of its employees. It is a workforce made infinitely stronger by its diversity, the very diversity that helped make this country great. The Federal Government that is now charging into the new millennium is one focused on quality, effectiveness and customer service, and one that is better equipped to recruit and retain a high quality workforce of the future.

In the coming year, we will continue focusing on ways to give Federal managers the tools they need to recruit and retain a high quality workforce. The Federal Government must have effective strategies for competing in the strong labor market. An important step in improving the Federal Government recruitment position was taken by President Clinton on July 7, 2000, in signing Executive Order 13162, establishing the Federal Career Intern Program. This program is designed to attract exceptional men and women to the Federal workforce who have a variety of experiences, academic disciplines and competencies, and to prepare them for careers in the analysis and execution of public programs. OPM will issue regulations to implement this important program, which will offer participants unrivaled professional experiences and training opportunities that are tailored to meet their professional goals.

To further enhance the Federal Government's ability to recruit and retain highly qualified professional, technical and administrative personnel, we will finalize regulations authorizing agencies to establish a program under which they may agree to repay all or part of any outstanding federally insured student loans, both for current agency employees and new recruits. These regulations will provide agencies with another important new tool for recruiting and retaining the best and brightest workers in today's competitive labor market.

We will propose regulations to give agencies greater flexibility to use recruitment and relocation bonuses and retention allowances by authorizing them to make such payments to their Federal Wage System employees. The regulations will also give agencies the flexibility to pay retention allowances to employees who are likely to leave their position for other Federal employment under a different pay system under certain limited conditions.

As the Federal Government continues to set the standard for compassionate, family-focused work environments, anticipated passage of supporting legislation will allow us to extend regulations authorized by the Child Care Tuition Assistance Program to permit agency use of appropriated funds for child care costs for lower income employees. Good quality child care can be prohibitively expensive, and we need to do everything we can to reduce costs and bring employees the peace of mind that comes with knowing their children are safe and in good hands. When human resource systems are designed to address employee needs such as assistance with child care costs, agencies immediately benefit by better recruitment and retention of qualified personnel, resulting in significant recruitment and training cost savings, lower absenteeism and improved employee morale.

We were pleased to announce recently that Federal employees will soon be able to use pretax dollars to pay for their health insurance premiums under the Federal Employees' Health Benefits Program. The President's FY 2001 Budget endorsed health insurance premium conversion to recognize that Federal employees are the key to effective Government performance and to enable the Government to attract and retain a high-quality work force.

Premium conversion will enable Executive Branch employees to pay their Federal Employees' Health Benefits Program premiums on a pretax basis. These regulations will take advantage of current tax law to allow more than 1.5 million Federal employees, representing over 3 million lives including dependents, to enjoy a benefit already available to most employees in the private sector and in State and municipal governments. As a result, the Federal Government will be a more competitive employer and health insurance will become more affordable for Federal employees and their families.

OPM also expects to introduce legislation to provide additional tools and flexibilities to enhance Federal human resource management for the future. As new legislation is enacted, OPM will prepare the necessary implementing regulations.

Under the leadership of President Clinton and Vice President Gore, our Government is more effective and responsive to the needs of the people we serve. Federal employees are focused like never before on innovation and productivity because they work for an employer that seeks and encourages excellence, an employer that demonstrates by its actions that it values their contributions, and an employer that understands the needs of the American worker in this new century.

The Office of Personnel Management will continue to accept the challenge of improving our human resource management systems in order to attract and keep the best possible talent, to promote fairness and diversity, to preserve the merit-based civil service system that serves as the cornerstone of our democracy, and to create a Government that truly serves our citizens.

OPM

PROPOSED RULE STAGE

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150. RECRUITMENT AND RELOCATION BONUSES AND RETENTION ALLOWANCES

Priority:

Other Significant

Legal Authority:

5 USC 5753; 5 USC 5754

CFR Citation:

5 CFR 575

Legal Deadline:

None

Abstract:

These proposed regulations would provide agencies with greater flexibility

in the use of recruitment and relocation bonuses and retention allowances. This proposal would amend the regulations to allow agencies to pay recruitment, relocation, and retention payments to Federal Wage System employees. The proposed regulations would also provide agencies with the flexibility to pay retention allowances to employees who are likely to leave their position for other Federal employment under a different pay system under certain limited conditions.

Statement of Need:

Agencies have specifically requested these proposed regulatory changes to provide them with additional flexibility to help recruit and retain Federal employees.

Summary of Legal Basis:

The governing United States Code provisions are 5 U.S.C. 5753 and 5 U.S.C. 5724.

Alternatives:

Other alternatives, such as authorizing the use of special salary rates, were considered and rejected because they were either inappropriate, too costly, or did not offer the flexibility agencies were seeking.

Anticipated Cost and Benefits:

The proposed regulations would help agencies recruit and retain critical employees and avoid the costs related to employee turnover (e.g., reduced productivity, increased or prolonged recruitment actions, training new employees). Because the proposed regulations expand the circumstances under which recruitment and relocation bonuses and retention allowances may be paid, it is possible that the costs associated with these payments may increase. However, since agencies have the discretion to use these recruitment and retention incentives, we cannot specifically predict or quantify these costs.

Risks:

These proposed regulations would delegate to agencies increased authority to pay recruitment and retention incentives to employees under certain, limited circumstances. We will continue to ensure agencies do not violate the merit systems principles and prohibited personnel practices under 5 U.S.C. 2301 and 2302 when using these new authorities through our monitoring and oversight responsibilities.

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Jeanne D. Jacobson
Workforce Compensation and Performance Service
Office of Personnel Management
Office of Compensation Administration
1900 E Street NW.
Washington, DC 20415
Phone: 202 606-2858
Fax: 202 606-0824
Email: payleave@opm.gov

RIN: 3206–AJ08

OPM

FINAL RULE STAGE

151. ● REPAYMENT OF STUDENT LOANS

Priority:

Other Significant

Legal Authority:

5 USC 5379

CFR Citation:

5 CFR 537

Legal Deadline:

None

Abstract:

These regulations implement Public Law 101-510 (codified as 5 U.S.C. 5379), which authorizes agencies to establish a program under which they may agree to repay all or part of any outstanding Federally insured student loan(s) in order to recruit or retain highly qualified professional, technical, or administrative personnel. The regulation will provide agencies with a tool for recruiting and retaining the best and brightest workers from today's competitive labor market.

Statement of Need:

These regulations will help agencies compete for highly qualified employees in today's competitive labor market.

Summary of Legal Basis:

These provisions are governed by title 5, United States Code, section 5379.

Alternatives:

These regulations are one of several flexibilitities agencies may use when trying to attract or retain individuals to Federal service for whom the government has a special need.

Anticipated Cost and Benefits:

As a retention incentive, the proposed regulations will help agencies avoid the costs related to employee turnover (e.g., reduced productivity, increased or prolonged recruitment actions, training new employees).

Agency use of this incentive is discretionary (both in terms of the number of employees receiving the benefit and the amount each employee may receive). Therefore, we cannot quantify the costs associated with implementation of these regulations.

Risks:

These proposed regulations give agencies the authority to use a new recruitment and retention incentive. The regulations require that agencies do not violate the merit systems principles and prohibited personnel practices under 5 U.S.C. 2301 and 2302 when using this new authority.

Timetable:

Action	Date	FR Cite
NPRM	06/22/00	65 FR 38791
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Mike Mahoney
Employment Service, Staffing Policy Division
Office of Personnel Management
1900 E Street NW.
Washington, DC 20415
Phone: 202 606-0830
Fax: 202 606-0023

RIN: 3206–AJ12

OPM

152. ● IMPLEMENTATION OF PREMIUM CONVERSION FOR EXECUTIVE BRANCH FEDERAL EMPLOYEES PARTICIPATING IN THE FEDERAL EMPLOYEES' HEALTH BENEFITS (FEHB) PROGRAM

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

26 USC 125

CFR Citation:

5 CFR 890

Legal Deadline:

None

Abstract:

At the President's direction, the Office of Personnel Management (OPM) is issuing regulations under the Federal Employees' Health Benefits (FEHB) Program to enable employees of all Executive Branch agencies to pay their share of FEHB premiums with pre-tax dollars in accordance with section 125 of the Internal Revenue Code. OPM is simultaneously amending salary allotment regulations at 5 CFR 550, because employees participating in premium conversion must allot a portion of salary to their employing agency that agencies will then use to pay the employee share of FEHB premiums. The regulations establish the basic rules under which premium conversion will operate beginning in October 2000.

Statement of Need:

In his 2001 Budget, the President directed OPM to implement health insurance premium conversion to bring the Federal Government in line with common private-sector employer practices. Over 60 million private sector employees with employment-based health insurance pay their premiums with pre-tax dollars. These regulations will take advantage of current tax law to allow more than 1.5 million Federal employees, representing more than 3 million lives including dependents, to have the same benefit as private sector workers. As a result, the Federal Government will be a more competitive employer and health insurance will become more affordable for Federal employees.

Summary of Legal Basis:

Premium conversion plans are a type of ''cafeteria plan'' that qualifies for special tax treatment under section 125 of the Internal Revenue Code.

Alternatives:

OPM met with those Federal agencies that have previously implemented a premium conversion plan: the U.S. Postal Service, the Federal Judiciary, and some small Executive Branch agencies with independent compensation-setting authority. OPM studied the range of implementation issues that these organizations encountered; from payroll system changes and educational outreach, to complying with tax code requirements. OPM also hired a contractor with substantial experience in employee benefits tax compliance to write a plan document that conforms to IRS section 125 rules. These regulations reflect the ''best practices'' of other employers in terms of premium conversion program development and implementation.

Anticipated Cost and Benefits:

Given the present tight labor market conditions, the Federal Government, like all employers, must use every means possible to attract and retain highly skilled employees. Premium conversion plans are a widely available employee benefit that lowers individual tax liability. This regulation will eliminate a competitive disadvantage in the Federal Government's compensation package and will increase employee satisfaction.

The costs associated with this regulation are the start-up costs to implement the premium conversion program; the decrease in Medicare, Social Security, and income taxes paid by Federal employees; and the decrease in Federal employer payments to the Medicare and Social Security trust funds.

OPM estimates the start-up cost to be $3 million in 2001, with $2.5 million coming from agency costs to update payroll systems to accommodate the program and $5 million from educational outreach programs. In fiscal year 2001, the tax benefit to employees is estimated to be about $670 million: $550 million in Federal income taxes; $85 million in Social Security taxes; and $35 million in Medicare taxes. The decrease in Federal employer payments to Social Security and Medicare trust funds is estimated to be $85 million and $35 million, respectively. Assuming that health insurance premiums will continue to increase at recent rates, the decrease in tax revenues attributable to premium conversion is expected to grow at a proportional rate in each subsequent year

Risks:

Premium conversion will assist the Federal Government in remaining competitive with other employers in attracting and retaining highly skilled employees. OPM has established a strategic compensation policy center to look at the best practices in pay, benefits and other forms of compensation in Federal, State and local governments, the private sector and foreign governments. OPM held a Strategic Compensation Conference 2000 on August 28-29 in Washington, D.C.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/19/00	65 FR 44644
Interim Final Rule Effective	09/18/00	
Final Action	11/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Abby L. Block
Chief, Insurance Policy Division,
Retirement and Insurance Group
Office of Personnel Management
Office of Insurance Programs
1900 E Street NW.
Washington, DC 20415
Phone: 202 606-0191

RIN: 3206–AJ17

OPM

153. ● EXCEPTED SERVICE; CAREER AND CAREER-CONDITIONAL EMPLOYMENT

Priority:

Other Significant

Legal Authority:

EO 13162

CFR Citation:

5 CFR 213; 5 CFR 315

Legal Deadline:

None

Abstract:

These regulations implement Executive Order 13162, which establishes the

Federal Career Intern Program. This program will be used to attract exceptional men and women to the Federal workforce who have diverse professional experiences, academic training, or competencies and prepare them for careers in analyzing and implementing public programs.

This regulation supports the Administration's effort to recruit the highest caliber people to the Federal Government, develop their professional abilities, and retain them in Federal departments and agencies.

Statement of Need:

Agencies have specifically requested an appointing authority that will enable them to attract and appoint exceptional individuals, who have a variety of experience, academic disciplines, or competencies necessary for the analysis and execution of their programs.

Summary of Legal Basis:

OPM has the authority under Civil Service Rule 6.1 to except positions from the competitive service when it determines that appointments to these positions through competitive examination is not practicable. Conversion to competitive civil service status is authorized under Executive Order 13162.

Alternatives:

Agencies are encouraged to utilize all available appointing authorities. These regulations provide agencies with one of several mechanisms to appoint individuals to Federal service at the entry level.

Anticipated Cost and Benefits:

Agencies will have the discretion to use this appointing authority for hiring individuals at a variety of grade levels. Therefore, we cannot quantify the costs associated with implementation of these regulations.

Risks:

These proposed regulations give agencies the authority to appoint individuals in the excepted service and noncompetitively convert them to the competitive service. The regulations require that agencies do not violate the merit systems principles and prohibited personnel practices under 5 U.S.C. 2301 and 2302 when using this new authority.

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Karen Jacobs
Employment Service, Staffing Policy Division
Office of Personnel Management
1900 E Street NW.
Washington, DC 20415
Phone: 202 606-0830
Fax: 202 606-0023

RIN: 3206–AJ28

BILLING CODE 6325–01–S

PENSION BENEFIT GUARANTY CORPORATION (PBGC)

Statement of Regulatory and Deregulatory Priorities

PBGC Insurance Programs

The Pension Benefit Guaranty Corporation (PBGC) administers two insurance programs for private defined benefit plans under title IV of the Employee Retirement Income Security Act of 1974 (ERISA): A single-employer plan termination insurance program and a multiemployer plan insolvency insurance program. The PBGC protects the pensions of nearly 43 million working men and women in about 39,000 private defined benefit plans, including about 1,800 multiemployer plans.

Under the single-employer program, the PBGC pays guaranteed and certain other pension benefits to participants and beneficiaries if their plan terminates with insufficient assets (distress and involuntary terminations). At the end of fiscal year 1999, the PBGC was trustee of almost 2,800 plans, and paid $902 million in benefits to about 230,000 people during 1999. Another 217,000 people will receive benefits when they retire in the future.

Most terminating single-employer plans terminate with sufficient assets to pay all benefits. The PBGC has administrative responsibility for these terminations (standard terminations), but its role is limited to seeing that proper procedures are followed and participants and beneficiaries receive their plan benefits.

The multiemployer program (which covers about 9 million workers and retirees in about 1,800 insured plans) is funded and administered separately from the single-employer program and differs in several significant ways. The multiemployer program covers only collectively bargained plans involving more than one unrelated employer. The PBGC provides financial assistance (in the form of a repayable loan) to the plan if the plan is unable to pay benefits at the guaranteed level. Guaranteed benefits are generally less than a participant's full benefit under the plan (and less than the single-employer guaranteed benefit). PBGC financial assistance occurs infrequently.

The PBGC receives no funds from general tax revenues. Operations are financed by insurance premiums, investment income, assets from pension plans trusteed by the PBGC, and recoveries from the companies formerly responsible for the trusteed plans.

To carry out these functions, the PBGC must issue regulations interpreting such matters as the termination process, establishment of procedures for the payment of premiums, and assessment and collection of employer liability.

Objectives and Priorities

PBGC regulatory objectives and priorities are developed in the context of the statutory purposes of title IV: (1) to encourage voluntary private pension plans, (2) to provide for the timely and uninterrupted payment of pension benefits to participants and beneficiaries, and (3) to maintain the premiums that support the insurance programs at the lowest possible levels consistent with carrying out the PBGC's statutory obligations (ERISA section 4002(a)).

The PBGC implements its statutory purposes by developing regulations designed: (1) to assure the security of the pension benefits of workers, retirees, and beneficiaries; (2) to improve services to participants; (3) to ensure that the statutory provisions designed to minimize losses for participants in the event of plan termination are effectively implemented; (4) to encourage the establishment and maintenance of defined benefit pension plans; (5) to facilitate the collection of monies owed to plans and to the PBGC, while keeping the related costs as low as possible; and (6) to simplify the termination process.

Legislative Initiatives

Since the early 1980s, there has been a gradual shift away from defined benefit pension plans in the private sector. The number of PBGC-insured defined benefit plans peaked in 1985 at about 112,000. Since then, there has been a sharp decline to about 40,000 plans in 1999.

This reduction has not been proportional across all plan sizes. Plans with fewer than 100 participants have shown the most marked decline, from about 90,000 in 1985 to less than 24,000 in 1999. There also has been a sharp decline for plans with between 100 and 999 participants, from more than 19,000 in 1985 to about 11,000 in 1999.

In marked contrast to the trends for plans with fewer than 1,000 participants, the number of plans with more than 1,000 participants has shown modest growth. Since 1980, the number of plans with between 1,000 and 9,999 participants has grown by about 6 percent, from 4,017 to 4,257 in 1999. The number of plans with at least 10,000 participants has grown from 469 in 1980 to 749 in 1999, an increase of nearly 60 percent.

The growth in the number of large plans is attributable to two factors. First, the rapid increase in inactive participants (retirees and separated vested participants) has pushed some plans into higher size categories. Second, there has been considerable plan merger activity over the 13-year period from 1985 through 1997.

In contrast to the dramatic reduction in the total number of plans, the total number of participants in PBGC-insured defined benefit plans has shown modest growth. In 1980, there were 35.5 million participants. By 1999, this number had increased to almost 43 million.

These numbers, however, mask the downward trend in the defined benefit system because total participants include not only active workers but also retirees (or their surviving spouses) and separated vested participants. The latter two categories of participants reflect past coverage patterns in defined benefit plans. A better forward-looking measure is the trend in the number of active participants, workers currently earning pension accruals. Here, the numbers continue to decline.

In 1988, there were 27.3 million active participants in defined benefit plans; by 1996 (the latest data available), this number had fallen to 22.6 million, a decrease of more than 17 percent. At the same time, the number of inactive participants has been growing. In 1980, inactive participants accounted for only 23 percent of total participants in defined benefit plans. By 1988, this number had increased to 31 percent; and by 1996, more than 45 percent of the participants in defined benefit plans were inactive participants. If this trend continues, by the year 2003, the number of inactive participants will exceed the number of active workers.

The President's budget for fiscal year 2001 includes numerous provisions to encourage the expansion of retirement plan coverage, including under defined benefit plans. These provisions include:

- A simplified defined benefit plan called SMART (Secure Money Annuity or Retirement Trust) for small businesses with 100 or fewer employees;
- A reduced PBGC premium of $5 per participant for the first 5 years of a small business's new plan and phase-in of the variable-rate premium over 5 years for new plans of all sizes;
- Expansion of the missing participants clearinghouse for terminating single-employer defined benefit plans

insured by the PBGC to other terminating plans—multiemployer defined benefit pension plans insured by the PBGC, certain other defined benefit pension plans not insured by the PBGC, and defined contribution plans;
- Simplified rules governing the PBGC's guarantee of benefits for a partial owner of a company and the allocation of plan assets to the benefits of these owner-employees; and
- Increasing the PBGC's benefit guarantee for multiemployer plans, which has been at the same level since 1980, from the current maximum guarantee of $5,850 to $12,870 (the guarantee increase would require no change in the multiemployer premium rate).

Regulatory and Deregulatory Initiatives

The PBGC has focused on changes that would simplify the rules and reduce regulatory burden. For example, over the past few years, the PBGC has reduced penalties for late premiums that are paid before the PBGC notifies the plan of the delinquency, extended the time limits for various actions required to terminate a fully funded single-employer plan in a standard termination, stopped the reduction of monthly benefits under its actuarial recoupment method once the nominal amount of the benefit overpayment is repaid, provided participants with benefits valued up to $5,000 in PBGC-trusteed plans with the choice of receiving their benefit in the form of an annuity or a lump sum, and extended the filing date for PBGC premiums to match the latest Form 5500 filing date.

In FY 2000, the PBGC:
- Amended its premium regulation to encourage self-correction of premium underpayments by making it easier to qualify for safe-harbor penalty relief (final rule, November 26, 1999).
- Simplified its valuation assumptions by adopting a single set of assumptions for allocation purposes (final rule, March 17, 2000).
- Assured the public that it intended to continue to calculate and publish its lump sum interest rates indefinitely and amended its regulations to make it easier for practitioners to refer to those rates (final rule, March 17, 2000).
- Solicited public comment on benefit valuation and payment issues relating to terminated cash balance plans that use variable indices to determine future retirement benefits (request for comments, July 6, 2000).

The PBGC is continuing to review its regulations to look for further simplification opportunities. The PBGC's regulatory plan for October 1, 2000, to September 30, 2001, consists of one significant regulatory action.

PBGC

PROPOSED RULE STAGE

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154. ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS; VALUATION OF BENEFITS AND ASSETS

Priority:

Other Significant

Legal Authority:

29 USC 1302(b)(3); 29 USC 1341; 29 USC 1301(a); 29 USC 1344; 29 USC 1362

CFR Citation:

29 CFR 4044 subpart B

Legal Deadline:

None

Abstract:

The Pension Benefit Guaranty Corporation is considering amending its benefit valuation and asset allocation regulations by adopting more current mortality tables and otherwise simplifying and improving its valuation assumptions and methods.

Statement of Need:

The PBGC's regulations prescribe rules for valuing a terminating plan's benefits for several purposes, including (1) determining employer liability and (2) allocating assets to determine benefit entitlements. The PBGC's interest assumption for valuing benefits, when combined with the PBGC's mortality assumption, is intended to reflect the market price of single-premium, nonparticipating group annuity contracts for terminating plans. In developing its interest assumptions, the PBGC uses data from surveys conducted by the American Council of Life Insurance. The PBGC currently uses a mortality assumption based on the 1983 Group Annuity Mortality Table in its benefit valuation and asset allocation regulations (29 CFR parts 4044 and 4281).

In May 1995, the Society of Actuaries Group Annuity Valuation Table Task Force issued a report that recommends new mortality tables for a new Group Annuity Reserve Valuation Standard and a new Group Annuity Mortality Valuation Standard. In December 1996, the National Association of Insurance Commissioners adopted the new tables as models for determining reserve liabilities for group annuities. The PBGC is considering incorporating these tables into its regulations and making other modifications.

Summary of Legal Basis:

The PBGC has the authority to issue rules and regulations necessary to carry out the purposes of title IV of ERISA.

Alternatives:

Not yet determined.

Anticipated Cost and Benefits:

Cost estimates are not yet available. However, the PBGC expects that this regulation will not have a material effect on costs.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
ANPRM	03/19/97	62 FR 12982
ANPRM Comment Period End	05/19/97	
NPRM	07/00/01	
NPRM Comment Period End	09/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

James L. Beller
Attorney
Pension Benefit Guaranty Corporation
Office of the General Counsel
1200 K Street NW
Washington, DC 20005-4026
Phone: 202 326-4024
TDD Phone: 800 877-8339
Fax: 202 326-4112

RIN: 1212–AA55

BILLING CODE 7708–01–S

SMALL BUSINESS ADMINISTRATION (SBA)

Statement of Regulatory Priorities

Overview

The Small Business Administration (SBA) continues to focus its regulatory efforts towards delivering sound economic development programs to small businesses through streamlined, customer-oriented regulations.

SBA began its efforts to streamline SBA regulations in 1994 in response to a Presidential directive to all agencies to review, revise, and eliminate regulations. SBA followed the directive, thoroughly reviewed all regulations, and by 1996, revised the bulk of SBA's regulations. The revised regulations are less burdensome, more ''user-friendly,'' and provide for more efficient operations. The regulations incorporate SBA's mission to ensure access to capital to our Nation's small businesses.

SBA's Regulatory Plan

Program for Investment in Microentrepreneurs Act (PRIME)

The SBA is proposing regulations that set forth PRIME's requirements for qualified Microenterprise Development Organizations (MDOs) to: (1) Train and provide technical assistance to disadvantaged microentrepreneurs; (2) build MDOs' capacity to give disadvantaged microentrepreneurs such training and technical assistance; (3) research and develop best practices for training and technical assistance; and (4) perform such other activities as the Administrator or designee determines are consistent with the Act. SBA will award a minimum of 75 percent of available funds to MDOs to use for training and technical assistance to disadvantaged microentrepreneurs. At a minimum, another 15 percent will be used to build MDOs' capacity to give more training and technical assistance. SBA will use the remaining funds to make grants for research and development on best practices or other purposes to improve MDOs' services to PRIME's ultimate beneficiaries–disadvantaged microentrepreneurs.

SBA

PROPOSED RULE STAGE

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155. ● PRIME ACT GRANTS

Priority:

Other Significant

Legal Authority:

15 USC 634(b)(6); PL 106-102

CFR Citation:

13 CFR 119

Legal Deadline:

None

Abstract:

The U.S. Small Business Administration is proposing regulations to add a new part 119 to set up the Program for Investment in Microentrepreneurs Act (''PRIME'' or ''the Act''). The proposed regulation sets forth the Act's grant requirements for qualified Microenterprise Development Organizations (''MDOs'') to: (1) Train and provide technical assistance to disadvantaged microentrepreneurs; (2) build MDOs' capacity to give disadvantaged microentrepreneurs such training and technical assistance; (3) research and develop best practices for training and technical assistance; and (4) perform such other activities as the Administrator or designee determines are consistent with the Act. SBA will award a minimum of 75 percent of available funds to MDOs to use for training and technical assistance to disadvantaged microentrepreneurs. At a minimum, another 15 percent will be used to build MDOs' capacity to give more training and technical assistance. SBA will use the remaining funds to make grants for research and development on best practices or other purposes to improve MDOs' services to PRIME's ultimate beneficiaries-disadvantaged microentrepreneurs.

Statement of Need:

Congress recognized that many disadvantaged microentrepreneurs lack sufficient training and education to gain access to capital and to conduct other activities necessary to establish, maintain, and expand their businesses. It enacted the Program for Investment in Microentrepreneurs Act (''PRIME'' or ''the Act'') to augment training and technical assistance under the Small Business Act and other legislation. PRIME grants to qualified Microenterprise Development Organizations (MDOs) will help meet training and technical assistance needs for disadvantaged microentrepreneurs, thereby encouraging entrepreneurship and capital formation at the community level.

Summary of Legal Basis:

The Program for Investment in Microentrepreneurs Act (''PRIME'' or ''the Act'') was created by title VII of the Gramm-Leach-Bliley Act, Public Law 106-102, enacted November 12, 1999 (113 Stat. 1471). The Act sets forth requirements for qualified Microenterprise Development Organizations (''MDOs'') to: (1) Train and provide technical assistance to disadvantaged microentrepreneurs; (2) build MDOs' capacity to give disadvantaged microentrepreneurs such training and technical assistance; (3) research and develop best practices for training and technical assistance; and (4) perform such other activities as the Administrator or designee determines are consistent with the Act.

The Act directs SBA to award a minimum of 75 percent of available funds to MDOs to use for training and technical assistance to disadvantaged microentrepreneurs and, at a minimum, another 15 percent to be used to build MDOs' capacity to give more training and technical assistance. The remaining funds are for grants for research and development on best practices or other purposes to improve MDOs' services to PRIME's ultimate beneficiaries-disadvantaged microentrepreneurs.

Alternatives:

Not applicable.

Anticipated Cost and Benefits:

PRIME grants will enable MDOs to reach more disadvantaged microentrepreneurs with training and technical assistance, which will make a difference in their ability to start, grow, and sustain microenterprises in economically distressed, high unemployment areas.

Risks:

Not applicable.

Timetable:

Action	Date	FR Cite
NPRM	10/10/00	65 FR 60256
NPRM Comment Period End	11/09/00	
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

Federal

Agency Contact:

Jane Palsgrove Butler
Associate Administrator for Financial Assistance
Small Business Administration
409 Third Street SW
Washington, DC 20416
Phone: 202 205-6490

RIN: 3245–AE52

BILLING CODE 8025–01–S

SOCIAL SECURITY ADMINISTRATION (SSA)

Statement of Regulatory Priorities

The Social Security Administration (SSA) administers the retirement, survivors, and disability insurance programs under title II of the Social Security Act (the Act), and the Supplemental Security Income (SSI) program under title XVI of the Act. Generally, SSA's regulations do not impose burdens on the private sector or on State or local governments. Our regulations codify the requirements for eligibility and entitlement to benefits under the programs that we administer.

Our eight entries for the Regulatory Plan represent areas of major importance to the administration of the retirement, survivors, disability, and SSI benefit programs.

One of SSA's most important initiatives is to assure that Social Security (SSDI) and Supplemental Security Income (SSI) beneficiaries with disabilities who want to work have the opportunity to do so. Included in this year's Plan are two final regulations that will provide more choices for people with disabilities who seek Return-to-Work services so that they may become self-sufficient. One regulation implements legislation, The Ticket to Work and Work Incentives Improvement Act of 1999, which removes barriers to work for individuals with disabilities. The other increases the monthly substantial gainful activity amount and the minimum amount that we consider as showing that a person is performing services, and then automatically increases both these amounts each year based on the national average wage index. This same regulation also increases the maximum monthly Student Earned Income Exclusion Amount and then increases that maximum amount annually using the consumer price index.

We are currently preparing two proposed regulations to improve the disability process. One would implement elements of the redesigned disability claims process that have been tested and found to further redesign goals. The other will update the cardiovascular listing to reflect advances in medical knowledge, treatment, and methods of evaluating cardiovascular impairments.

Providing world-class service to our customers remains a principal objective of SSA. One of the items in the Plan, Expansion of the Use of Video Teleconference Technology in Hearings Before Administrative Law Judges of the Social Security Administration, is expected to improve customer service by providing faster access to a hearing.

Effective stewardship of SSA programs requires mechanisms to assure that benefits are used to meet the needs of beneficiaries who are not able to manage their own benefits due to legal incompetence or medical infirmity. A proposed regulation will make improvements to the representative payment procedures needed to assure program integrity. This regulation reflects certain provisions of Public Laws 101-508, 103-296, 104-121, and 105-33.

We have also included in this year's Plan, two regulations that provide SSA with additional tools to strengthen the integrity of the Social Security and SSI programs. One is a proposed regulation that implements a provision of the Foster Care Independence Act of 1999, authorizing SSA to obtain information from financial institutions in order to determine initial or continuing eligibility for SSI benefits. The other is a final regulation that permits SSA to recover SSI overpayments by adjusting the amount of Social Security benefits payable to the individual under title II of the Act.

We continue to work diligently to improve our program benefit regulations and to develop partnerships with large segments of the community of stakeholders interested in Social Security programs. We expect that these partnerships will contribute to the successful development of our Regulatory Plan entries.

SSA

PROPOSED RULE STAGE

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156. OASDI AND SSI; EXPANSION OF THE USE OF VIDEO TELECONFERENCE TECHNOLOGY IN HEARINGS BEFORE ADMINISTRATIVE LAW JUDGES OF THE SOCIAL SECURITY ADMINISTRATION (737P)

Priority:

Other Significant

Legal Authority:

42 USC 205(a); 42 USC 205(b); 42 USC 902(a)(5); 42 USC 1383

CFR Citation:

20 CFR 404.929; 20 CFR 404.936(b); 20 CFR 404.936(c); 20 CFR 404.936(d)(8)(New); 20 CFR 404.938; 20 CFR 416.1429; 20 CFR 416.1436(b); 20 CFR 416.1436(c); 20 CFR 416.1436(d)(8)(New); 20 CFR 416.1438

Legal Deadline:

None

Abstract:

We propose to amend our regulations to permit us to conduct hearings before an administrative law judge (ALJ) by video teleconference (VTC). We also propose to add new sections to the regulations that will state the conditions for an ALJ to find good cause to change the time and place of a hearing if we schedule a VTC hearing, and the individual tells us he/she does not want a VTC hearing.

Statement of Need:

Our regulations provide for a hearing in person before an ALJ. Traditionally, this has meant that the individual requesting a hearing and the ALJ were present in the same room. The proposed changes will allow us to schedule a VTC hearing without requiring prior written consent, and set out the right to decline such a hearing. We believe that conducting hearings by VTC will improve our efficiency and allow us to serve our customers better.

Providing VTC hearings is one initiative of the Hearings Process Improvement Plan we issued in August 1999. We expect that the plan, when fully implemented, will reduce the average processing time for hearings from 314 days in Fiscal Year 1999 to less than 200 days in Fiscal Year 2002, and allow us to issue hearing decisions to 30 percent of requestors within 120 days from the date of the request for hearing. The VTC provision would aid in this reduction by eliminating much of the time some ALJ's must spend to travel to remote sites to conduct hearings face-to-face.

Summary of Legal Basis:

None.

Alternatives:

Require participation in a scheduled VTC hearing, i.e., no right to decline a VTC hearing.

Anticipated Cost and Benefits:

Improved customer service by providing faster access to a hearing.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	
Final Action	04/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Lawrence V. Dudar
Social Insurance Specialist
Social Security Administration
Office of Process and Innovation Management
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 966-5995

RIN: 0960–AE97

SSA

157. TICKET TO WORK AND SELF-SUFFICIENCY PROGRAM (TICKET TO WORK AND WORK INCENTIVES IMPROVEMENT ACT OF 1999) (767P)

Priority:

Economically Significant. Major under 5 USC 801.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 902(a)(5); 42 USC 1320b-19; PL 106-170, sec 101

CFR Citation:

20 CFR 404.316; 20 CFR 404.337; 20 CFR 404.352; 20 CFR 404.401; 20 CFR 404.902; 20 CFR 404.1586; 20 CFR 404.1590; 20 CFR 404.1596; 20 CFR 404.1597; 20 CFR 404.2101; 20 CFR 416.101; 20 CFR 416.213; 20 CFR 416.708; 20 CFR 416.990; 20 CFR 416.1321; 20 CFR 416.1328; 20 CFR 416.1331; 20 CFR 416.1338; 20 CFR 416.1402; 20 CFR 416.1701 to 416.1715; 20 CFR 416.2040; 20 CFR 416.2201

Legal Deadline:

Final, Statutory, December 17, 2000, One year after the date of enactment of Public Law 106-170.

Sec. 1148(l) of the Social Security Act (42 USC 1320b-19(1), as added by sec. 101(a) of PL 106.170, requires SSA to prescribe regulations to carry out the Ticket to Work and Self-Sufficiency Program.

Abstract:

These proposed regulations would implement the Ticket to Work and Self-Sufficiency Program under section 1148 of the Act, as added by section 101(a) of Public Law 106-170. They also will carry out provisions of sections 101(d) and (e) of Public Law 106-170 relating to the implementation of that program and section 101(b) providing conforming amendments to the Act. One of SSA's most important initiatives is to assure that Social Security (SSDI) and Supplemental Security Income (SSI) beneficiaries with disabilities who want to work have the opportunity to do so. Individuals with disabilities face multiple barriers in attempting to return to work. The Ticket to Work and Self-Sufficiency Program, under section 1148 of the Act, removes such barriers by providing beneficiaries with disabilities with the opportunity to obtain rehabilitation, employment and support services from an approved vocational rehabilitation provider of their choice.

Statement of Need:

This regulatory action is necessary to implement Ticket to Work and Self-Sufficiency Program under section 1148 of the Act, as added by section 101(a) of Public Law 106-170. Changes to existing regulations also are needed to reflect amendments to the Act made by section 101(b) of Public Law 106-170.

Regulations to implement the Ticket to Work and Self-Sufficiency Program are required under section 1148(1) of the Act and section 101(e) of Public Law 106-170. Section 101(e)(2) of Public Law 106-170 provides that the matters to be addressed in the regulations shall include the following:

(1) The form and manner in which tickets to work and self-sufficiency may be distributed to beneficiaries pursuant to section 1148(b)(1) of the Act;

(2) The format and wording of such tickets, which shall incorporate by reference any contractual terms governing service by employment networks under the Program;

(3) The form and manner in which State agencies may elect participation in the Ticket to Work and Self-Sufficiency Program pursuant to section 1148(c)(1) of the Social Security Act and provision for periodic opportunities for exercising such elections;

(4) The status of State agencies under section 1148(c)(1) at the time that State agencies exercise elections under that section;

(5) The terms of agreements to be entered into with program managers pursuant to section 1148(d) of the Act, including:

(a) The terms by which program managers are precluded from direct participation in the delivery of services pursuant to section 1148(d)(3) of the Act;

(b) Standards that must be met by quality assurance measures referred to in paragraph (6) of section 1148(d) of the Act and methods of requirement of employment networks; and

(c) The format under which dispute resolution will operate under section 1148(d)(7) of the Act;

(6) The terms of agreements to be entered into with employment networks pursuant to section 1148(d)(4) of the Act, including:

(a) The manner in which service areas are specified pursuant to section 1148(f)(2)(A) of the Act;

(b) The general selection criteria and the specific selection criteria that are applicable to employment networks under section 1148(f)(1)(C) of the Act in selecting service providers;

(c) Specific requirements relating to annual financial reporting by employment networks pursuant to section 1148(f)(3) of the Act; and

(d) The national model to which periodic outcomes reporting by employment networks must conform under section 1148(f)(4) of the Act;

(7) Standards that must be met by individual work plans pursuant to section 1148(g) of the Act, including:

(a) The form and manner in which elections by employment networks of payment systems are to be exercised pursuant to section 1148(h)(1)(A) of the Act;

(b) The terms that must be met by an outcome payment system under section 1148(h)(2) of the Act;

(c) The terms that must be met by an outcome-milestone payment system under section 1148(h)(3) of the Act;

(d) Any revision of the percentage specified in paragraph (2)(C) of section 1148(h) of the Act or the period of time specified in paragraph (4)(B) of such section 1148(h) of the Act; and

(e) Annual oversight procedures for such systems; and

(8) Procedures for effective oversight of the Program by the Commissioner of Social Security, including periodic reviews and reporting requirements.

Regulations also are needed to implement section 1148(i) of the Act, which provides for the suspension of continuing disability reviews during any period for which an individual is using, as defined by the Commissioner, a ticket to work and self-sufficiency issued under section 1148.

Summary of Legal Basis:

Section 1148(i) of the Act, as added by section 101(a) of Public Law 106-170, and sections 101(d)(5) and (e) of Public Law 106-170 require this regulatory action.

Alternatives:

None. This regulatory action is necessary to implement provisions of section 101 of Public Law 106-170.

Anticipated Cost and Benefits:

We anticipate substantial costs to start up the program and potential savings in later years. The anticipated benefits of this legislation include allowing individuals with disabilities to seek the services necessary to obtain employment and reduce their dependency on cash benefit programs, including SSI and SSDI.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	
Final Action	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State

Agency Contact:

Suzanne DiMarino
Social Insurance Specialist
Social Security Administration
Office of Process and Innovation Management
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 965-1769

Geoffrey Funk
Social Insurance Specialist
Social Security Administration
Office of Employment Support Programs
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 965-9010

RIN: 0960–AF11

SSA

158. TITLE XVI, CROSS-PROGRAM RECOVERY (746F)

Priority:

Other Significant

Legal Authority:

42 USC 1320b-17

CFR Citation:

20 CFR 404.401; 20 CFR 416.558; 20 CFR 416.570; 20 CFR 416.572

Legal Deadline:

None

Abstract:

These final regulations deal with the recovery of overpayments under the Supplemental Security Income (SSI) Program. They will permit SSA to recover SSI overpayments by adjusting the amount of Social Security benefits payable to the individual under title II of the Act. This collection practice will be limited to individuals who are not currently eligible to receive an SSI cash benefit. Also, the amount of the title XVI overpayment recoverable in a month would be limited to 10 percent of the amount payable under title II, unless the overpaid person (or his or her spouse) willfully misrepresented or concealed material information about the overpayment. In that case, the entire title II benefit amount would be adjusted to recover the overpayment.

Statement of Need:

Section 8 of Public Law 105-306, effective October 28, 1998, added a new section 1147 to the Act that gives SSA an additional debt collection tool to recover title XVI overpayments. Under section 1147, SSA is permitted to recover SSI overpayments by adjusting the amount of any benefits payable to the overpaid person under title II of the Act, without his or her consent.

Summary of Legal Basis:

Section 8 of Public Law 105-306, effective October 28, 1998, added a new section 1147 to the Act that gives SSA an additional debt collection tool to recover title XVI overpayments.

Alternatives:

None.

Anticipated Cost and Benefits:

The program savings from increased collections as a result of implementation of Public Law 105-306 are $15 million in each of FY 2001 through FY 2003, $40 million in FY 2004, and $30 million in FY 2005, for a total increase of $115 million over 5 years. The administrative savings estimate for FY 2001 through FY 2005 is less than $5 million.

Risks:

There are no significant concerns, since the proposed changes reflect the current law with respect to recovery of title XVI overpayments from title II benefits.

Timetable:

Action	Date	FR Cite
NPRM	10/03/00	65 FR 58970
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Edward Johns
Financial Management Analyst
Social Security Administration
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 965-0392

Robert J. Augustine
Social Insurance Specialist
Social Security Administration
Office of Process and Innovation Management
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 966-5121

RIN: 0960–AF13

SSA

159. ● ACCESS TO INFORMATION HELD BY FINANCIAL INSTITUTIONS (815P)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 1383(e); PL 106-169, sec 213

CFR Citation:

20 CFR 416.200; 20 CFR 416.206 to 416.208; 20 CFR 416.217

Legal Deadline:

None

Abstract:

We are proposing to implement a new law that will enhance our access to bank account information of Supplemental Security Income (SSI) applicants or recipients and other individuals whose income and resources we treat as belonging to the applicant or recipient.

Statement of Need:

This proposed regulation is required to implement section 213 of Public Law 106-169, the Foster Care Independence Act of 1999.

Summary of Legal Basis:

Required by section 213 of Public Law 106-169.

Alternatives:

None.

Anticipated Cost and Benefits:

Costs and benefits are undetermined at this time.

Risks:

Undetermined at this time.

Timetable:

Action	Date	FR Cite
NPRM	12/00/00	
Final Action	06/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

None

Federalism:

Undetermined

Agency Contact:

Kathy Branch
Social Insurance Specialist
Social Security Administration
Office of Program Benefits
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 965-8766

Lawrence V. Dudar
Social Insurance Specialist
Social Security Administration
Office of Process and Innovation Management
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 966-5995

RIN: 0960–AF43

SSA

160. • IMPLEMENTING THE REDESIGNED DISABILITY PROCESS (816P)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Reinventing Government:

This rulemaking is part of the Reinventing Government effort. It will revise text in the CFR to reduce burden or duplication, or streamline requirements.

Legal Authority:

42 USC 301

CFR Citation:

20 CFR 404; 20 CFR 416

Legal Deadline:

None

Abstract:

We propose to implement elements of the redesigned disability claims process that have been tested and found to further redesign goals. Specifically, we propose to revise the disability determination process by: (1) eliminating the reconsideration step of the appeals process; (2) enhancing the roles of the disability examiner and medical/psychological consultant to streamline the process and make more effective use of the doctor's knowledge and expertise; and (3) increasing claimant contact and explanation of the requirements for disability. We propose to implement the redesigned process in phases; the existing process will remain in effect for States that have not yet adopted the redesigned process.

Statement of Need:

This regulation is necessary to make most effective use of resources in order to ensure that disabled claimants are found disabled at the earliest point in the claims process, and to better communicate the basis for our determinations.

Summary of Legal Basis:

None.

Alternatives:

The Agency is considering various options for phasing in the implementation of the redesigned disability claims process.

Anticipated Cost and Benefits:

Unknown at present—the cost/benefit analysis has not yet been completed.

Risks:

Not yet established.

Timetable:

Action	Date	FR Cite
NPRM	01/00/01	
Final Action	10/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

State, Federal

Additional Information:

RIN 0960-AE73 was merged into this regulation on August 14, 2000.

Agency Contact:

Robert J. Augustine
Social Insurance Specialist
Social Security Administration
Office of Process and Innovation Management
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 966-5121

Phillip Landis
Director, Disability Process Redesign Staff
Social Security Administration
Office of Disability
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 965-7414

RIN: 0960–AF44

SSA

161. • REVISED MEDICAL CRITERIA FOR DETERMINATION OF DISABILITY, CARDIOVASCULAR SYSTEM AND RELATED CRITERIA (826P)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 405; 42 USC 1302; 42 USC 1383

CFR Citation:

20 CFR 404.1500, app 1

Legal Deadline:

None

Abstract:

Listings 4.00 and 104.00 of appendix 1 to the disability regulation at 20 CFR

404.1501 through 404.1599 describe those cardiovascular impairments that are considered severe enough to prevent a person from doing any gainful activity or, for a child claiming SSI payments under title XVI, that causes marked and severe functional limitations. Comprehensive revisions to these listings are being made to ensure that the medical evaluation criteria are up to date and consistent with the latest advances in medicine. The SSI program incorporates by reference and uses the same medical criteria as the old-age, survivors, and disability insurance program.

Statement of Need:

These regulations are necessary to update the cardiovascular listing to reflect advances in medical knowledge, treatment, and methods of evaluating cardiovascular impairments.

Summary of Legal Basis:

Administrative—not required by statute or court order.

Alternatives:

None.

Anticipated Cost and Benefits:

The proposed changes will have negligible program and administrative cost impact because, despite changes in terminology and emphasis, the proposed cardiovascular system listings describe a level of severity comparable to the level of severity contained in the current listings.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	06/00/01	
Final Action	09/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

None

Federalism:

Undetermined

Agency Contact:

Lawrence V. Dudar
Social Insurance Specialist
Social Security Administration
Office of Process and Innovation Management
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 966-5995

Bonnie Davis
Social Insurance Specialist
Social Security Administration
Office of Disability
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 965-4172

RIN: 0960–AF48

SSA

162. ● REPRESENTATIVE PAYMENT UNDER TITLE II AND XVI OF THE SOCIAL SECURITY ACT

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

42 USC 401(j); 42 USC 902(a)(5); 42 USC 405 note; 42 USC 421 note; 42 USC 1383(a)(2); 42 USC 1383(d)(1); 42 USC 404(f); 42 USC 405(a); 42 USC 405(b); 42 USC 405(d) to 405(h); 42 USC 405(j); 42 USC 405(k); 42 USC 421; 42 USC 425

CFR Citation:

20 CFR 404.902; 20 CFR 404.2011; 20 CFR 404.2022; 20 CFR 404.2024; 20 CFR 404.2025; 20 CFR 404.2030; 20 CFR 404.2041; 20 CFR 404.2050; 20 CFR 416.611; 20 CFR 416.622; 20 CFR 416.624; 20 CFR 416.625; 20 CFR 416.630

Legal Deadline:

None

Abstract:

Effective stewardship of SSA programs requires mechanisms to assure that benefits are used to meet the needs of beneficiaries who are not able to manage their own benefits due to legal incompetence or medical infirmity. Congress determined that improvements to the representative payment procedures were needed to assure program integrity. These regulations are required to further our program integrity efforts.

Statement of Need:

These regulations, which reflect certain provision of Public Law 101-508, 103-296, 104-121, and 105-33, modify existing representative payee procedures by: (1) requiring the Social Security Administration to do a more extensive investigation of representative payee applicants, generally limiting to 1 month the deferral or suspension of direct payment of benefits pending selection of a payee; (2) providing stricter standards in determining the fitness of representative payee applicants to manage benefit payments on behalf of beneficiaries; (3) requiring SSA to repay the beneficiary or an alternate payee, an amount equal to any misused funds resulting from SSA's negligent failure to investigate or monitor a representative payee; (4) granting certain payees the authority to collect a fee from beneficiaries, changing how SSA treats persons with a drug addition or an alcohol condition; and (5) requiring SSA to compile and maintain a centralized file of certain beneficiary and payee information.

These regulations are needed to reflect certain provisions of Public Law 101-508 (OBRA '90), 103-296, 104-121 and 105-33. Sections 205(a), 1102 and 1631(d) of the Act give the Commissioner broad power to make rules and carry out these provisions.

Summary of Legal Basis:

These regulations implement section 5105 of Public Law 101-508, section 210 of Public Law 103-296, section 105 of Public Law 104-121, section 5525 of Public Law 105-33.

Alternatives:

None.

Anticipated Cost and Benefits:

Any costs associated with these regulations are reflected in the President's budget as part of legislative implementation. They are required to further our program integrity efforts.

Risks:

None.

Timetable:

Action	Date	FR Cite
NPRM	10/00/00	
Final Action	06/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

No

Government Levels Affected:

None

Federalism:

Undetermined

Agency Contact:

Betsy Byrd
Program Policy Specialist
Social Security Administration
Office of Program Benefits
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 965-7981

Lawrence V. Dudar
Social Insurance Specialist
Social Security Administration
Office of Process and Innovation Management
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 966-5995

RIN: 0960–AF49

SSA

FINAL RULE STAGE

163. OASDI, AND SSI FOR THE AGED, BLIND AND DISABLED; SUBSTANTIAL GAINFUL ACTIVITY AMOUNTS; ''SERVICES'' FOR TRIAL WORK PERIOD PURPOSES—MONTHLY AMOUNTS; STUDENT-EARNED INCOME EXCLUSION (777F)

Priority:

Other Significant

Legal Authority:

42 USC 402; 42 USC 405(a); 42 USC 405(b); 42 USC 405(d) to 405(h); 42 USC 416(i); 42 USC 421(a); 42 USC 421(i); 42 USC 422(c); 42 USC 423; 42 USC 425; 42 USC 902(a)(5); 42 USC 1382; 42 USC 1382c; 42 USC 1382h; 42 USC 1383(a); 42 USC 1383(c); 42 USC 1383(d)(1); 42 USC 1383b

CFR Citation:

20 CFR 404.1574; 20 CFR 404.1592; 20 CFR 416.974; 20 CFR 1112

Legal Deadline:

None

Abstract:

These final regulations will automatically increase the average monthly earnings guide used to determine whether work done by persons with impairments other than blindness is substantial gainful activity (SGA). As of July 1999, average monthly earnings above $700 are considered SGA. These final regulations increase the minimum monthly amount of earnings that demonstrate that a person is performing services during a trial work period, and automatically increase the amount each subsequent year. Additionally, these final regulations update the amount of the student-earned-income exclusion (SEIE) and adjust the SEIE for inflation annually, using the consumer price index.

Statement of Need:

This regulation fulfills SSA's promise to the public that was provided in conjunction with the regulation that increased the SGA level effective July 1999, that SSA would consider adopting appropriate changes to SGA in the future. Additionally, this regulation should encourage SSA beneficiaries with disabilities to return to work; a major initiative of the Agency.

Summary of Legal Basis:

None

Alternatives:

None

Anticipated Cost and Benefits:

This regulation has been determined to have a negligible cost for the Agency. The public will be able to enjoy the benefits of having the various items addressed in the regulation: the monthly SGA amount; the amount of the TWP service month; and the SEIE automatically increased each year, if appropriate, rather than waiting for SSA to take steps to increase these items.

Risks:

None

Timetable:

Action	Date	FR Cite
NPRM	08/11/00	65 FR 49208
Final Action	01/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Robert J. Augustine
Social Insurance Specialist
Social Security Administration
Office of Process and Innovation Management
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 966-5121

Ray Marzoli
Social Insurance Specialist
Social Security Administration
Office of Employment Support Systems
6401 Security Boulevard
Baltimore, MD 21235-6401
Phone: 410 965-9826

RIN: 0960–AF12

BILLING CODE 4191–02–S

COMMODITY FUTURES TRADING COMMISSION (CFTC)

Statement of Regulatory Priorities

The mission of the Commodity Futures Trading Commission is to protect market users and the public from fraud, manipulation, and abusive practices related to the sale of commodity futures and options and to foster open, competitive, and financially sound commodity futures and option markets. The Commission's objectives are to: (1) Foster futures and option markets that accurately reflect the forces of supply and demand for the underlying commodity and are free of disruptive activity; (2) oversee markets which can be used effectively by producers, processors, financial institutions, and other firms for the purposes of price discovery and risk shifting; (3) promote compliance with, and deter violations of, Federal commodities laws; (4) require commodities professionals to meet high standards; (5) provide a forum for effectively and expeditiously handling customer complaints against persons or firms registered under the Commodity Exchange Act; (6) ensure sound financial practices of clearing organizations and firms holding customer funds; (7) promote and enhance effective self-regulation of the commodity futures and option markets; (8) facilitate the continued development of an effective, flexible regulatory environment responsive to evolving market conditions; and (9) promote markets free of trade practice abuses.

CFTC

FINAL RULE STAGE

164. ● NEW REGULATORY FRAMEWORK FOR MULTILATERAL TRANSACTION EXECUTION FACILITIES, INTERMEDIARIES, AND CLEARING ORGANIZATIONS

Priority:

Other Significant

Legal Authority:

7 USC 6, 6c, 6i, 7, 7a, 8, 12a

CFR Citation:

17 CFR 1.37; 17 CFR 1.41; 17 CFR 5; 17 CFR 15; 17 CFR 20; 17 CFR 36 to 38

Legal Deadline:

None

Abstract:

The Commission is proposing a new regulatory framework to apply to multilateral transaction execution facilities that trade futures and commodity options. Specifically, the Commission is proposing to replace the current ''one-size-fits-all'' regulation for futures markets with broad, flexible ''Core Principles,'' and to establish three regulatory tiers for markets: recognized futures exchanges, derivatives transaction facilities, and exempt multilateral transaction facilities. The Core Principles are tailored to match the degree and manner of regulation to the varying nature of the products traded thereon, and to the sophistication of customers.

Statement of Need:

The futures markets are poised to undergo rapid change as they continue to meet the competitive challenges posed by technological advances. The new framework will provide U.S. futures exchanges the flexibility to respond to these challenges by offering a level of regulation tailored to three alternative types of markets.

Summary of Legal Basis:

The new framework constitutes a broad exemption under the authority of Section 4(c) of the Commodity Exchange Act, 7 USC 6(c). The Commission was encouraged in this undertaking by the other Federal financial regulators that comprise the President's Working Group on Financial Markets and by the Chairmen of the Commission's oversight committees.

Alternatives:

In the absence of this proposed new regulatory framework, the exchanges would continue to be governed by a ''one-size-fits-all'' regulatory scheme.

Anticipated Cost and Benefits:

The anticipated benefits of the proposed framework are that it will promote innovation and competition in the trading of derivatives and permit futures markets the flexibility to respond to technological and structural changes. At the same time, the framework is designed to reduce systemic risk and protect customers.

Risks:

The U.S. futures exchanges currently face competitive challenges which the new regulatory framework is intended to help the exchanges address. The new regulatory framework is also designed to reduce systemic risk and protect customers.

Timetable:

Action	Date	FR Cite
NPRM	06/22/00	65 FR 38986
NPRM Comment Period Extended	08/11/00	65 FR 49208
NPRM Comment Period End	08/21/00	
Final Action	10/00/00	
Final Active Effective	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Paul M. Architzel
Chief Counsel, Division of Economic Analysis
Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st Street NW
Washington, DC 20581
Phone: 202 418-5260
Fax: 202 418-5527
Email: parchitzel@cftc.gov

Riva Spear Adriance
Attorney Advisor, Division of Trading and Markets
Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st Street, NW
Washington, DC 20581
Phone: 202 418-5494
Fax: 202 418-5536
Email: radriance@cftc.gov

Alan L. Seifert
Deputy Director, Division of Trading and Markets
Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st Street, NW
Washington, DC 20581
Phone: 202 418-5490
Email: aseifert@cftc.gov

RIN: 3038–AB55

CFTC

165. ● RULES RELATING TO INTERMEDIARIES OF COMMODITY INTEREST TRANSACTIONS

Priority:

Other Significant

Legal Authority:

7 USC 2; 7 USC 6; 7 USC 6b; 7 USC 6d; 7 USC 6f; 7 USC 6m; 7 USC 6n; 7 USC 12a; 7 USC 23

CFR Citation:

17 CFR 1.3, 1.10, 1.17, 1.20, 1.25-1.29; 17 CFR 1.33, 1.46, 1.52, 1.55; 17 CFR 3.1, 3.10, 3.32, 3.34; 17 CFR 4.10, 4.24, 4.34; 17 CFR 140.91; 17 CFR 3 app B; 17 CFR 155.6; 17 CFR 166.5

Legal Deadline:

None

Abstract:

The Commission has undertaken an extensive review of the rules promulgated under the Commodity Exchange Act. As part of this regulatory reform process, the Commission is proposing to amend several of its rules relating to intermediation of commodity interest transactions. If adopted, these rule amendments would provide for: (1) An expanded range of instruments in which FCMs may invest customer funds; (2) simplified registration procedures for FCMs and IBs operating exclusively on recognized derivatives transaction facilities (DTFs) for institutional customers; (3) elimination of the required submission of a certified financial report as part of FCM or IB registration procedures; (4) effective replacement of the required ethics training for Commission registrants with a Statement of Acceptable Practices; (5) amendment of the definition of ''principal'' in Rule 3.1(a) to exclude certain officers of a firm; (6) simplification of account opening procedures by permitting a single signature for all documents (except for a predispute arbitration agreement in the case of a non-institutional customer) and elimination of the prescribed disclosure statement delivery requirement for governmental entities; (7) codification of a previous interpretation permitting electronic transmission of account statements; and (8) greater customer choice concerning the close-out of offsetting positions.

Statement of Need:

U.S. futures markets are poised to undergo rapid change as they continue to meet the competitive challenges posed by technological advances and increasing globalization. These technological advances allow for greater trading opportunities through electronic platforms as opposed to traditional floor-based exchanges. Consequently, the role and functions of intermediaries in futures transactions are subject to change. To facilitate the continued development of an effective, flexible regulatory environment responsive to evolving market conditions, the Commission is proposing a package of rule amendments applicable to intermediaries. These rule amendments are being proposed in conjunction with proposals for new regulatory frameworks for multilateral transaction execution facilities and for clearing organizations. Taken together, these regulatory initiatives are intended to promote innovation and to maintain U.S. competitiveness, and at the same time reduce systemic risk and protect customers.

Summary of Legal Basis:

Section 8a(5) of the Commodity Exchange Act authorizes the Commission to promulgate such rules as, in the judgment of the Commission, are reasonably necessary to effectuate any of the provisions or to accomplish any of the purposes of the Act. Various other provisions of the Act grant the Commission general rulemaking authority concerning registration, recordkeeping, and investment of customer funds.

Alternatives:

Absent the Commission's regulatory reform initiative, U.S. intermediaries would face increasingly greater challenges from technological advances and global competition. U.S. intermediaries would also be deprived of the advantages of a modernized, flexible, and streamlined regulatory environment.

Anticipated Cost and Benefits:

As a financial regulator, the Commission is acutely aware of the costs of regulation. Throughout its history, the Commission has been sensitive to the costs of its proposed rules as compared to the benefits of such rules.

Risks:

In addition to the formal comment period on the proposals, the Commission held an open hearing on the proposals. Further, prior to the drafting of the proposals, a Commission staff task force engaged in extensive consultations with interested parties in developing a report to the Commission's Congressional oversight committees entitled A New Regulatory Framework. All of these efforts are intended to minimize the risk that the Commission's rules are not sufficiently flexible to respond to evolving market conditions.

Timetable:

Action	Date	FR Cite
NPRM	06/22/00	65 FR 39008
NPRM Comment Period Extended	08/11/00	65 FR 49208
NPRM Comment Period End	08/21/00	
Final Action	10/00/00	
Final Action Effective	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Lawrence B. Patent
Associate Chief Counsel, Division of Trading and Markets
Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st Street NW.
Washington, DC 20581
Phone: 202 418-5439
Email: lpatent@cftc.gov

RIN: 3038–AB56

CFTC

166. • NEW REGULATORY FRAMEWORK FOR CLEARING ORGANIZATIONS

Priority:

Other Significant

Legal Authority:

7 USC 2; 7 USC 6(c); 7 USC 7a; 7 USC 12a(5)

CFR Citation:

17 CFR 39

Legal Deadline:

None

Abstract:

The Commission is proposing new part 39 of its rules that would apply to clearing organizations, as defined in the proposed rules. This proposal, centered on broad, flexible core principles, is part of an initiative proposing a new regulatory framework applicable to multilateral transaction execution facilities and market intermediaries in addition to clearing organizations. The new regulatory framework is designed to promote innovation, maintain U.S. competitiveness, and move the Commission from a direct to an oversight regulator. Part 39 of this

framework will establish core principles, supplemented with statements of guidance, that must be met by organizations that clear or desire to clear futures and options contracts executed on derivatives transaction execution facilities or recognized futures exchanges.

Statement of Need:

The performance of the functions involved in clearing for futures and options markets can raise concerns regarding concentration of financial risk and credit risk in a single entity. Organizations clearing contracts executed on derivatives transaction facilities and recognized futures exchanges should be subject to regulatory oversight to ensure that such facilities are capitalized sufficiently and that they establish and implement a risk management program that is designed to control the credit concentration risk associated with centralized clearing.

Summary of Legal Basis:

The Commission currently oversees the clearing organizations that are associated or affiliated with U.S. futures and option exchanges. The Commission was encouraged in this undertaking by the President's Working Group on Financial Markets and by the Chairmen of the Commission's Congressional oversight committees.

Alternatives:

In the absence of this proposed new regulatory framework and Part 39, the Commission would continue to oversee U.S. futures and options clearing organizations and otherwise carry out its Congressional mandate in its current style as a direct, design-based regulator.

Anticipated Cost and Benefits:

As a financial regulator, the Commission is acutely aware of the costs of regulation. Throughout its history, the Commission has taken into account the costs of its proposed regulations in order to ensure that the benefits of its regulations outweigh the costs. No aspect of Part 39 would adversely affect small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601-611 (1988).

Risks:

By promulgating broad, flexible, core principles for organizations that clear futures and options contracts on derivatives transaction facilities and recognized futures exchanges, the Commission is able to effectively ensure that such facilities are adequately capitalized, implement satisfactory risk management programs, and are otherwise subject to an appropriate level of regulatory oversight.

Timetable:

Action	Date	FR Cite
NPRM	06/22/00	65 FR 39027
NPRM Comment Period Extended	08/11/00	
NPRM Comment Period End	08/21/00	
Final Action	10/00/00	
Final Action Effective	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Lois J. Gregory
Special Counsel, Division of Trading and Markets
Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st Street NW
Washington, DC 20581
Phone: 202 418-5260
Fax: 202 418-5536
Email: lgregory@cftc.gov

RIN: 3038–AB57

CFTC

167. • EXEMPTION FOR BILATERAL TRANSACTIONS

Priority:

Other Significant

Legal Authority:

7 USC 2; 7 USC 6; 7 USC 6c; 7 USC 12a

CFR Citation:

17 CFR 35

Legal Deadline:

None

Abstract:

The Commission is proposing to expand and to clarify the operation of the Part 35 Swaps Exemption, including the availability of clearing for these transactions. These proposed amendments would provide greater legal certainty to the OTC markets and reduce systemic risk.

Statement of Need:

The Part 35 amendments respond to changes that have occurred in the over-the-counter market since the Commission adopted its swaps policy statement in 1989, and its subsequent Part 35 swaps exemption in 1993.

Summary of Legal Basis:

The amendments are being proposed under Section 4(c) of the Commodity Exchange Act, 7 USC 6(c), which grants the Commission broad exemptive authority. The Commission was encouraged in this undertaking by the other Federal financial regulators that comprise the President's Working Group on Financial Markets and by the Chairmen of the Commission's oversight committees.

Alternatives:

In the absence of the proposed amendments, the Commission's regulations would not be responsive to the changes that have occurred in the OTC market over the past decade.

Anticipated Cost and Benefits:

The anticipated benefits of the proposed rules are to enhance legal certainty and reduce systemic risk for transactions entered into in the OTC market.

Risks:

The proposal is designed to enhance legal certainty and reduce systemic risk for transactions entered into in the OTC market.

Timetable:

Action	Date	FR Cite
NPRM	06/22/00	65 FR 39033
NPRM Comment Period Extended	08/11/00	
NPRM Comment Period End	08/21/00	
Final Action	10/00/00	
Final Action Effective	12/00/00	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Paul M. Architzel
Chief Counsel, Division of Economic Analysis
Commodity Futures Trading Commission
Three Lafayette Centre
1155 21st Street NW
Washington, DC 20581
Phone: 202 418-5260
Fax: 202 418-5527
Email: parchitzel@cftc.gov

RIN: 3038–AB58

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CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

Statement of Regulatory Priorities

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of death and injury associated with consumer products. To achieve this goal, the Commission:

- participates in the development or revision of voluntary product safety standards;
- develops mandatory product safety standards or banning rules when other, less restrictive, efforts are inadequate to address a safety hazard;
- obtains repairs, replacement, or refund of the purchase price for defective products that present a substantial product hazard; and
- develops information and education campaigns about the safety of consumer products.

When deciding which of these approaches to take in any specific case, the Commission gathers the best available data about the nature and extent of the hazard presented by the product. The Commission then analyzes this information to determine the best way to reduce the hazard in each case. The Commission's rules require the Commission to consider, among other factors, the following criteria when deciding the level of priority for any particular project:

- frequency and severity of injury;
- causality of injury;
- chronic illness and future injuries;
- costs and benefits of Commission action;
- unforeseen nature of the risk;
- vulnerability of the population at risk;
- probability of exposure to the hazard.

Additionally, if the Commission proposes a mandatory safety standard for a particular product, the Commission is generally required to make statutory cost/benefit findings and adopt the least burdensome requirements that adequately protect the public.

The Commission's statutory authority requires it to rely on voluntary standards rather than mandatory standards whenever a voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury and it is likely that there will be substantial compliance with the voluntary standard. As a result, much of the Commission's work involves cooperative efforts with other participants in the voluntary standard-setting process rather than promulgating mandatory standards.

In fiscal year 2001, the Commission's significant rulemaking activities will involve: (1) addressing risks of fire associated with ignition of upholstered furniture by small open flames, and (2) a requirement that drugs, when switched by the Food and Drug Administration from prescription to over-the-counter status, remain in child-resistant packaging to protect children from being poisoned by gaining access to the drugs.

The emphasis on these rulemaking activities in the Commission's FY 2001 regulatory plan is consistent with the Commission's statutory mandate and its criteria for setting priorities.

CPSC

PROPOSED RULE STAGE

168. FLAMMABILITY STANDARD FOR UPHOLSTERED FURNITURE

Priority:

Economically Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

15 USC 1193, Flammable Fabrics Act

CFR Citation:

16 CFR 1640

Legal Deadline:

None

Abstract:

On June 15, 1994, the Commission published an advance notice of proposed rulemaking (ANPRM) to begin a proceeding for development of a flammability standard to address risks of death, injury, and property damage from fires associated with ignition of upholstered furniture by small open-flame sources such as matches, lighters, or candles. This ANPRM was issued after the Commission granted part of a petition requesting development of a mandatory flammability standard to address risks of injury from ignition of upholstered furniture by: (1) small open-flame sources; (2) large open-flame sources; and (3) cigarettes. The Commission voted to deny that part of the petition requesting development of a mandatory standard to address hazards associated with ignition of upholstered furniture by large open-flame sources. The Commission also voted to defer a decision on that part of the petition requesting development of a standard to address cigarette ignition, and directed the staff to report to the Commission on the effectiveness of, and the extent of industry compliance with, a voluntary program to reduce risks of ignition of upholstered furniture by cigarettes. The Commission staff developed a draft standard to address ignition of upholstered furniture by small open-flame sources.

On March 2, 1998, the Commission voted to defer action on small open-flame sources and gather additional information on the potential toxicity of flame-retardant chemicals that might be used to meet a standard. A public hearing on this subject was held May 5-6, 1998. The staff is analyzing data from the hearing and completing other technical studies. In CPSC's 1999 appropriations legislation, Congress directed the Commission to contract with the National Academy of Sciences (NAS) for an independent study of potential health hazards associated with the use of flame retardant chemicals that might be used in upholstered furniture fabrics to meet a CPSC standard. The draft NAS report was completed and forwarded to Congress in April 2000; the final NAS report was published in July 2000. The report concluded that of 16 flame-retardant chemicals reviewed, 8 could be used in upholstered furniture fabrics without presenting health hazards to consumers. Additional exposure studies were recommended for the remaining eight chemicals. The report indicates that a number of suitable flame-retardant treatments are available; these include treatments already in use in various textile products, including upholstered furniture sold in the United Kingdom to meet existing U.K. flammability regulations.

CPSC is also considering possible impacts of flame-retardant chemical use on worker safety and the environment. At the CPSC staff's request, the National Institute of Occupational Safety and Health is assessing potential worker exposure to and risks from certain flame-retardant chemicals that may be used by textile and furniture producers to comply with an upholstered furniture flammability standard. The CPSC staff is also working with the Environmental Protection Agency to consider possible controls on flame-retardant compounds used in residential upholstered furniture fabrics under that agency's Toxic Substances Control Act Authority. Upon completion of its chemical risk assessment and other technical activities, the CPSC staff will

present alternatives for future action by the Commission.

Statement of Need:

In 1997, approximately 650 deaths, more than 1,500 injuries, and about $225 million in property damage resulted from 11,500 residential fires in the United States in which upholstered furniture was the first item to ignite. The total societal cost attributable to upholstered furniture fires was approximately $3.75 billion in 1997. This total includes fires ignited by small open-flame sources, large open-flame sources, and cigarettes. Of these, open-flame fires accounted for approximately 80 deaths, 500 injuries and $64 million in property losses.

Summary of Legal Basis:

Section 4 of the Flammable Fabrics Act (FFA) (15 USC 1193) authorizes the Commission to issue a flammability standard or other regulation for a product of interior furnishing if the Commission determines that such a standard is ''needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death or personal injury, or significant property damage.''

The Commission's regulatory proceeding could result in several actions, one of which could be the development of a mandatory standard requiring that upholstered furniture sold in the United States meet mandatory labeling requirements, resist ignition, or meet other performance criteria under test conditions specified in the standard.

Alternatives:

The ANPRM stated that the Commission was considering the following alternatives:

(1) The Commission could issue a mandatory flammability standard if the Commission finds that such a standard is needed to address an unreasonable risk of the occurrence of fire from ignition of upholstered furniture by small open-flame sources;

(2) The Commission could issue mandatory requirements for labeling of upholstered furniture, in addition to, or as an alternative to, the requirements of a mandatory flammability standard;

(3) The Commission could terminate the proceeding for development of a flammability standard and rely on a voluntary standard if a voluntary standard would adequately address the risk of fire and substantial compliance with such a standard is likely to result; and

(4) The Commission could terminate the proceeding and withdraw the ANPRM.

Anticipated Cost and Benefits:

The estimated annual cost of imposing a mandatory standard to address ignition of upholstered furniture by small open-flame sources will depend upon the test requirements imposed by the standard and the steps manufacturers take to meet those requirements. Again, depending upon the test requirements, a small open-flame standard could also reduce cigarette-ignited fire losses, the societal cost of which was over $2 billion in 1997. For this reason, the potential benefits of a mandatory standard to address the risk of ignition of upholstered furniture by small open-flame sources could be significant, even if the standard did not prevent all such fires started by open-flame sources.

Risks:

The estimated total cost to society from all residential fires associated with upholstered furniture was $3.75 billion in 1997.

Societal costs associated with upholstered furniture fires are among the highest associated with any product subject to the Commission's authority. A standard has the potential to reduce these societal costs.

Timetable:

Action	Date	FR Cite
ANPRM	06/15/94	59 FR 30735
ANPRM Comment Period End	08/15/94	
Staff Briefing of Commission on NPRM	12/18/97	
Commission Voted To Defer Action Pending Results of Toxicity Hearing	03/02/98	
Commission Hearing May 5 & 6, 1998 on Possible Toxicity of Flame Retardant Chemicals	03/17/98	63 FR 13017
NAS Study Completed (Required by Congress)	07/10/00	
Staff Sends Briefing Package to Commission	02/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Federalism:

Undetermined

Agency Contact:

Dale R. Ray
Project Manager, Directorate for Economic Analysis
Consumer Product Safety Commission
Washington, DC 20207
Phone: 301 504-0962
Email: dray@cpsc.gov

RIN: 3041–AB35

CPSC

169. ● REQUIREMENT FOR SPECIAL PACKAGING OF ORAL PRESCRIPTION DRUGS THAT ARE GRANTED OVER-THE-COUNTER STATUS BY THE FOOD AND DRUG ADMINISTRATION

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

15 USC 1471, Poison Prevention Packaging Act

CFR Citation:

Not Yet Determined

Legal Deadline:

None

Abstract:

On June 23, 2000, the Commission directed the CPSC staff to draft a notice of proposed rulemaking to require that the child-resistant packaging requirements for oral prescription drugs continue when the active chemicals are granted over-the-counter (OTC) status by the Food and Drug Administration (FDA). The current regulations under the Poison Prevention Packaging Act (PPPA) require child-resistant packaging of most oral prescription drugs. However, when the FDA allows an oral prescription drug to be sold OTC, child-resistant packaging of that drug is no longer required. When the Commission finds that a particular switched OTC drug requires child-resistant packaging because it may cause serious injury or serious illness, it must issue an individual rule, which may not take effect for several years after the switch.

On August 30, 2000, the Commission issued a proposed rule that would automatically require drugs that have been switched after the effective date

of the rule to be in child-resistant packaging. Under the proposed rule, drugs switched by FDA from prescription to OTC before the effective date of the rule would not automatically have to be in child-resistant packaging. This proposed rule provides that those companies that believe their drug product does not need to be in child-resistant packaging can provide information to the Commission, as they do currently under the PPPA oral prescription drug rule, to demonstrate either: (1) that the drug product will not injure children if it is marketed in non-child-resistant packaging, or (2) that child-resistant packaging is not technically feasible, practicable, or appropriate for the oral drug when marketed as an OTC product. If the Commission agrees, it will by rule exempt the drug product from the PPPA requirements. The Federal Register notice also proposes to revoke 16 CFR 1702.16(b) to allow petitions for exemptions from child-resistant packaging requirements to be submitted and considered by the Commission before the new drug applications (NDA) are approved by the FDA. This would decrease the potential financial and regulatory burdens to the drug company associated with a post-marketing package change.

The notice issued by the Commission includes proposed findings that child-resistant packaging for these products is technically feasible, practicable, and appropriate, as well as necessary to protect children from serious personal injury and illness resulting from handling, using, or ingesting the drug products. It is anticipated that this proposed rule would not create a financial burden on small companies.

Statement of Need:

Currently CPSC must issue a separate child-resistant packaging requirement for each oral prescription drug that the FDA allows to be sold OTC in order to maintain child-resistant packaging for that drug. This proposed rule would require that children have the same protection when the drugs are more widely available as OTC products as they had when the drugs were available only by prescription.

Summary of Legal Basis:

Section 3 of the PPPA, 15 U.S.C. 1472, authorizes the Commission to issue special packaging standards for household substances if it finds that special packaging is necessary to protect children from serious injury or illness and that special packaging is technically feasible, practicable, and appropriate.

Alternatives:

The Commission can either: (1) issue a final rule requiring that oral prescription drugs continue to require child-resistant packaging when they are granted OTC status by the FDA, or (2) continue to issue regulations on a case-by-case basis after the status of the drug products has been switched to OTC.

Anticipated Cost and Benefits:

This project supports the Commission's strategic goal of keeping children safe from poisoning hazards. Children would have the same protection when drugs are more widely available as OTC preparations as they had when the drugs were available only by prescription. In general, the incremental cost of child-resistant packaging is mimimal ($0.005-$0.02).

Risks:

For prescription medicines and aspirin alone, CPSC estimates that about 800 children's lives have been saved by the requirement for child-resistant packaging. However, there continues to be about 30 deaths and 1 million calls to poison control centers about poisonings to young children each year. Without this rule, there is the potential for certain oral drugs to be sold without child-resistant packaging when they are available as OTC drugs, even though they required special packaging as prescription drugs. Children are at risk for serious injury from ingesting these products if child-resistant packaging is not required.

Timetable:

Action	Date	FR Cite
Staff Briefing of Commission on Whether to Issue an NPRM	06/07/00	
Commission Decision to Prepare a Draft NPRM	06/23/00	
NPRM	08/30/00	65 FR 52678
NPRM Comment Period End	11/13/00	
Staff Sends Briefing Package to Commission	03/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

Agency Contact:

Suzanne Barone Ph.D.
Project Manager
Consumer Product Safety Commission
Directorate for Health Sciences
Washington, DC 20207
Phone: 301 504-0477
Email: sbarone@cpsc.gov

RIN: 3041–AB92

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FEDERAL ENERGY REGULATORY COMMISSION (FERC)

Statement of Regulatory Priorities

The Federal Energy Regulatory Commission regulates key interstate aspects of the electric power, natural gas pipeline, oil pipeline, and hydroelectric industries. The Commission seeks to protect customers using regulatory approaches that foster competitive markets whenever possible, assure access to reliable service at a reasonable price, and give full and fair consideration to environmental and community impacts in assessing the public interest of energy projects.

The 2000 regulatory priorities reflect the Commission's commitment to its strategic goals:

- promoting competitive markets;
- protecting customers;
- respecting the environment; and
- serving and safeguarding the public.

While much of the Commission's regulatory activity continues to be done in case-specific adjudications, the Commission has increasingly employed generic rulemakings to pursue its strategic goals and carry out its statutory responsibilities. With respect to many of the Commission's major policy initiatives, the Commission has completed the rulemaking process by issuing final rules and orders on rehearing in the past year. These important initiatives are now in the equally important rule implementation stage.

The industries the Commission regulates are changing very rapidly in response to increasing competition and environmental awareness. The Commission is responding by implementing the following key initiatives:

Energy Markets:

- Final Rule on Formation of Regional Transmission Organizations (Order No. 2000)
- Final Rule on Regulation of Natural Gas Transportation Services (Order No. 637)

Energy Projects:

- Policy Statement on Determining Need for New Pipeline Facilities
- Final Rule on Landowner Notification

Procedural Reforms:

- Rulemaking on Electronic Filing
- Rulemakings to Reengineer Reporting Requirements

The Commission has been innovative in using active outreach efforts to inform its generic policy development and its rulemaking efforts. For example, the Commission has had great success in using informal meetings with a wide variety of stakeholders to inform the development of its major rulemakings on regional transmission organizations (Order No. 2000) and on natural gas transportation policy (Order No. 637). The Commission has also used active outreach as a tool in promoting constructive implementation of Order No. 2000, assisting regional groups, as requested, in the development of regional transmission organization (RTO) proposals. Moreover, it has committed, in Order No. 637, to an ongoing dialogue with interested parties on possible further reforms for natural gas regulation.

Energy Markets

In carrying out its statutory responsibilities for economic regulation of interstate aspects of electricity and natural gas pipeline markets, the Commission is pursuing policies designed to promote competitive markets and protect customers. To support competition in electricity and natural gas markets, the Commission regulates access to and pricing of essential electricity transmission and natural gas transportation services so as to eliminate undue discrimination and mitigate market power. The Commission is implementing two major rulemaking initiatives to advance these important goals: one relating to formation of regional transmission organizations in the electric industry, and the other reforming regulation of the natural gas industry.

Regional Transmission Organizations; 1902-AB77, Docket No. RM99-2-000 (Order No. 2000). In December 1999, the Commission issued a Final Rule on Regional Transmission Organizations (RTOs). This rule is often referred to as Order 2000. The Commission supports the creation of RTOs to promote efficient operation of the transmission grid, eliminate residual discrimination by transmission owners, promote grid reliability, and facilitate regional grid planning. This rulemaking advances the Commission goal of promoting competition in bulk power markets as a means of encouraging efficient operation of, and investment in, generation and transmission facilities, and thereby reducing consumer prices.

The Commission added regulations under the Federal Power Act to facilitate the formation of RTOs. The Commission required each public utility that owns, operates or controls facilities for the transmission of electric energy in interstate commerce to make certain filings with respect to forming and participating in an RTO. The Commission also established certain minimum characteristics (independent governance; appropriate scope and regional configuration; adequate operational authority; and responsibility for short-term reliability) and functions (designing and administering tariffs; managing transmission congestion; addressing parallel path flow; providing ancillary services; operating an Open Access Same-Time Information System and determining available transmission capacity; monitoring markets; regional planning and expansion; and interregional coordination) that must be satisfied in order to be considered to be an RTO. The rule establishes a framework for supporting and encouraging voluntary RTO formation, including a commitment to consider applications for innovative ratemaking treatments from RTOs.

In February 2000, the Commission issued an order on rehearing making only minor changes to the rule (Order 2000-A). In Spring 2000, the Commission staff held five regional workshops to kick-off RTO formation efforts and staff has, where requested on an ongoing basis, provided assistance to regional efforts. This collaborative process to facilitate RTO formation has involved jurisdictional and nonjurisdictional utilities, state officials and other affected interest groups across the country.

Implementation of this rule to enable prompt RTO operation is expected to be a top priority on the Commission's agenda over the next year. Filings to establish RTOs or explaining why RTOs have not been formed are due in October 2000 and January 2001. Timely Commission action on these filings will be critical to enable RTOs to begin operation by December 2001 as contemplated by the rule.

Natural Gas Policy Initiative; 1902-AB74, Docket No. RM98-10-000 (Order No. 637). The Commission is implementing a natural gas policy initiative to improve the efficiency, transparency, and competitiveness of natural gas markets. Further, it is exploring expanded reliance on competitive market forces in its oversight of the natural gas transportation market.

As part of the natural gas initiative, the Commission issued a Final Rule in February 2000 establishing a more market-based approach to regulation of aspects of the short-term transportation market, while at the same time

continuing to protect captive customers against the exercise of market power. In the Final Rule, the Commission revised its pricing policy to enhance efficiency by temporarily lifting the price cap for short-term releases of capacity, and permitting pipelines to propose rates that vary seasonally or based on the duration of contracts. The Final Rule also adopted changes to the regulations regarding scheduling procedures, capacity segmentation and pipeline penalties to improve competition and efficiency across the pipeline grid. Finally, the Rule improves the Commission's reporting requirements to permit more effective market monitoring. The Commission affirmed and clarified the Final Rule in its orders on rehearing in May 2000 (Order No. 637-A) and July 2000 (Order No. 637-B)

In the year ahead the focus is expected to be on implementation of Order No. 637 and a more fundamental review of the approach to natural gas transportation regulation. Order No. 637 directed the pipelines to modify their tariffs to comply with Order No. 637, and the Commission is currently in the process of reviewing these compliance filings. In addition, the Final Rule states that the Commission will undertake, outside of this proceeding, a new process to evaluate the direction of future natural gas regulation. This process will involve Commission monitoring of the market (including an assessment of the temporary lifting of the price cap for short-term releases of capacity), technical conferences and other dialogue with the various industry segments, and, if appropriate, the establishment of new docketed proceedings.

Energy Projects

The Commission's rulemaking activities in the area of authorizing gas pipeline and hydroelectric project development are aimed at protecting the environment and the public, while at the same time serving customer interests and promoting competition. The key rulemakings in the energy projects area are: (1) a policy statement articulating the Commission's approach to determining need for new pipeline development; and (2) a rulemaking to give earlier notification to landowners affected by pipeline project proposals, to facilitate their participation in project review. The Commission has also adopted procedural rules designed to support constructive collaboration between pipeline developers and affected parties before the certificate application is filed.

Policy Statement on Determination of Need; 1902-AB86, Docket No. PL-3-000. In deciding whether a proposed pipeline project is required by the public convenience and necessity, the Commission has adopted a policy of considering not only the interests of the applicant and potential new customers, but also the interests of the applicant's existing customers, the captive customers of other pipelines that serve the market, landowners, and communities. One key element of the policy is that a project must not rely on subsidies from existing customers. With a policy against subsidies by captive ratepayers, the market will discipline projects that are not economically viable. Moreover, under this policy, construction projects that will have unmitigated adverse effects on relevant interests, including landowners and community interests, will be approved only if on balance the benefits outweigh the harm.

The new policy is designed to provide incentives for pipelines to eliminate or minimize adverse effects before filing, through correctly structured financial arrangements, careful project design, and negotiations with landowners. By working out contentious issues in advance and mitigating impacts where impacts cannot be avoided, the applicant can develop a record in support of the project, reducing time required for the Commission's deliberative process. This policy was adopted in September 1999, and was the subject of clarification in subsequent orders in February and July of 2000.

Landowner Notification, Expanded Categorical Exclusions, and Other Environmental Filing Requirements; 1902-AB83, Docket No. RM98-17-000. In October 1999, the Commission issued a final rule amending its regulations under the Natural Gas Act by adding certain early landowner notification requirements that will ensure that landowners who may be affected by a pipeline's proposal to construct natural gas pipeline facilities have sufficient opportunity to participate in the Commission's certificate process. The Commission also amended its regulations to provide pipelines with greater flexibility and to further expedite the certificate process. The Commission issued rehearing orders on this rule in March and June 2000.

Procedural Reforms

The Commission has recently undertaken several important initiatives to reform and streamline its procedures, with the goals of expediting Commission action, emphasizing use of alternative dispute resolution (ADR), and improving access to information. In 1999, for instance, the Commission adopted final rules reforming its complaint procedures to facilitate expedited review and encourage use of ADR; and its rules governing off-the-record communications designed to enhance the Commission's access to information consistent with preserving the fairness and integrity of the decisional process. The Commission is actively pursuing electronic filing as a means of cutting costs and improving access to information. The Commission also expects to undertake a systematic review of its reporting requirements to ensure that it has access to the information it needs for effective market oversight and eliminates the burden of filing information that is no longer needed for regulatory purposes.

Electronic Filing; 1902-AB-89, Docket No. PL98-1-001. The Commission has begun implementation of its electronic filing initiative by amending its rules to permit electronic service of documents. In October 2000 the Commission expects to expand this initiative to allow electronic filing of certain types of filings. These steps will reduce expenses involved with paper filings, such as copying and messenger services, and make information available more quickly.

Besides reducing the filing burden on industry, electronic filing will generate information more quickly for industry by making the content of filings available within minutes or hours, rather than days. Electronic notification of filings will take much less time than is necessary for paper notification, giving companies earlier access to filed information.

Reengineering of Reporting Requirements. The Commission is required to review its reporting requirements every three years pursuant to the Paperwork Reduction Act. Recently, these reviews have led to questions about whether certain reported information is needed for regulatory purposes and, if so, whether it can be submitted confidentially. Simultaneously, the Commission's new approach to energy market monitoring and oversight will likely require access to and assessment of new types of data. As a consequence, the Commission expects to undertake a systematic review of its current reporting requirements to determine what reported information is no longer needed and what unreported information is now needed for its

regulatory purposes. This effort may include multiple rulemakings. The Commission has committed to undertake one element of this review, related to Form 1 reports filed by electric utilities, by summer 2001.

BILLING CODE 6717–01–S

FEDERAL HOUSING FINANCE BOARD (FHFB)

Statement of Regulatory and Deregulatory Priorities

The Federal Housing Finance Board (Finance Board) is an independent agency that is charged under the Federal Home Loan Bank Act (Bank Act) with supervising and regulating the Nation's Federal Home Loan Bank (Bank) System. The Bank System comprises 12 regional Banks that are each owned by their member financial institutions and provide wholesale credit to members and certain nonmembers to be used for mortgage lending and related community lending activities. The Bank System also includes the Office of Finance, which issues Bank System consolidated obligations. The Finance Board is required to prepare the following Regulatory Plan pursuant to section 4 of Executive Order 12866.

As always, the Finance Board's highest regulatory priorities during the coming year are to ensure the safety and soundness of the Bank System and to ensure that the Banks fulfill their housing finance and community investment mission. In furtherance of these statutory mandates, the Finance Board plans one significant regulatory action during 2000-2001; that is, the finalization of regulations establishing a new capital structure for the Banks. This rulemaking is mandated by the Federal Home Loan Bank Modernization Act of 1999 (Modernization Act) and is described in detail below.

FHFB

PROPOSED RULE STAGE

170. MINIMUM CAPITAL REQUIREMENTS FOR THE FEDERAL HOME LOAN BANKS

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

12 USC 1426; 12 USC 1422b(a)

CFR Citation:

12 CFR 917; 12 CFR 925; 12 CFR 930; 12 CFR 931; 12 CFR 932; 12 CFR 933; 12 CFR 956; 12 CFR 960

Legal Deadline:

Final, Statutory, November 12, 2000.

Abstract:

The Finance Board issued a proposed rule to adopt regulations mandating a new capital structure for the Banks, as required by the Modernization Act. The rule would replace the Banks' existing ''subscription capital'' structure with a more modern, flexible risk-based capital structure for each of the Banks.

The Modernization Act requires that the Banks' existing subscription capital structure be replaced by a structure that may consist of two classes of capital stock: Class A, redeemable on six months' written notice to the Bank, and Class B, redeemable on five years' written notice to the Bank. Under the proposed rule, each Bank would be able to decide whether to issue either Class A or Class B stock, or both, and would have significant latitude in specifying the terms, voting rights and dividend preferences of each class of stock.

The proposed rule also reflects the requirement of the Modernization Act that each Bank maintain a ratio of total capital to total assets of at least five percent. Thereunder, each Bank would be permitted to weight its permanent capital (the amount of Class B stock plus retained earnings) at 1.5 times paid-in value, as long as its total capital, excluding such weighting, is not less than four percent of its total assets. The proposed rule would also require that each Bank have permanent capital at all times in amounts sufficient to meet the rule's risk-based capital requirements for credit risk, market risk and operations risk.

Finally, the proposed rule describes the required content of each Bank's ''capital structure plan.'' The Modernization Act requires that each Bank submit such a plan to the Finance Board for approval within 270 days of the publication of a final rule. The Modernization Act further provides for a transition period to the new capital structure of up to three years from the effective date of each Bank's capital structure plan.

Statement of Need:

Since the enactment of the Federal Home Loan Bank Act (Bank Act) in 1932, there has been a ''subscription'' structure for the capitalization of the Banks. Under this structure, the amount of capital stock each Bank issues to its member institutions is determined either as a percentage of the total mortgage assets of each member of the Bank, or the dollar amount of advances outstanding to each member, whichever is greater. Under the subscription capital structure, the amount of capital each Bank is required to hold bears no relationship to any risks posed by its operations.

The subscription capital structure has resulted in significant overcapitalization of the Banks in relation to their current operating risks. The amount of excess capital is a factor contributing to the increase in the amount of arbitrage investments made by the Banks; such as investments in money market instruments or mortgage-backed securities that do not advance the housing and community lending mission of the Banks. The substantial amount of nonmission investments held by the Banks collectively, though decreasing in recent years as a percentage of their assets, has been the subject of much criticism from the Administration and Congress, and was one issue that Congress intended to address by reforming the capital structure and other aspects of the Bank System as part of the Modernization Act.

The new statutory provisions mandate the replacement of the existing subscription capital structure over a period of up to several years with a more modern capital structure, incorporating risk-based and leverage capital requirements that are similar to those for depository institutions and the other housing government-sponsored enterprises (GSEs). The Modernization Act provides for a transition period to the new capital structure of up to approximately five years from the date of enactment, during which time the prior capital provisions are to remain in effect.

Summary of Legal Basis:

Under section 6(a) of the Bank Act, 12 U.S.C. 1426(a), as amended by the Modernization Act, the Finance Board is required to issue regulations prescribing uniform capital standards applicable to each Bank no later then November 12, 2000. These regulations must conform to the leverage capital, risk-based capital and capital stock requirements set forth in section 6(a). In addition, section 2B(a) of the Bank Act generally authorizes the Finance Board to promulgate such regulations as are necessary to carry out the provisions of the Bank Act. See 12 U.S.C. 1422b(a)(1).

The proposed rule originally provided for a 90-day comment period, ending on October 11, 2000, to allow for the adoption of a final rule by the November 12, 2000 statutory deadline. However, numerous commenters

requested that the agency extend the comment period to allow for more comments on and consideration of the complex issues addressed in the proposed rule. While mindful of the requirements of the Modernization Act, the Finance Board determined that it is in the best interest of the Banks, their members and the public to extend the comment period to November 20, 2000.

Alternatives:

To a significant extent, the parameters of the proposed capital regulations have been established by Congress and, therefore, are not subject to alternative resolutions devised by the Finance Board. However, the Finance Board will consider alternative approaches to a number of definitions and other issues that are not addressed expressly by statute.

As required by the Moderization Act, the regulations would establish risk-based capital requirements under which each Bank must maintain permanent capital in an amount sufficient to meet the credit, market and operations risks to which the Bank is exposed. Regarding credit risk, the proposed rule would assign to each category of the Bank investment a risk factor, weighted according to the estimated risk exposure. The market risk requirement would be determined using a portfolio stress test model devised by each Bank in accordance with the requirements of the rule. The Finance Board has solicited comments on the specific credit risk-weightings proposed for each asset category and on the requirements pertaining to the market risk model that each Bank must develop. The agency will consider any suggested alternative approches to these issues as it is developing a final rule.

As mandated by the Modernization Act, the proposed rule also would permit each Bank to issue either Class A stock or Class B stock (the characteristics of which are described above), or both, and would define the essential characteristics of both types of stock. The Finance Board has proposed that Class A stock have a par value of $100 per share, be issued at par value, and pay a stated dividend that has a priority over the payment of dividends on Class B stock. The agency has proposed that Class B stock have a par value that is determined by each Bank. In order to give each Bank the flexibility to inure its Class B stock with greater permanence by setting par value below the issue price, the Finance Board has proposed to permit Class B stock to be issued at a price determined by the Bank, which could be different from the par value.

Under the Act and the proposed rule, the Class B stock would confer an ownership interest in the retained earnings of the Bank upon payment of the issue price by a member. No member institution would be allowed to cast more than 20 percent of the votes in any election for the board of directors, but a Bank could establish a lower percentage limit in its capital structure plan. In addition, under the proposed rule, no member institution could hold more than 40 percent of any class of a Bank's stock. The Finance Board has requested comments on these elements of the capital stock voting structure and will consider any suggested alternative approaches in drafting the final rule.

Anticipated Cost and Benefits:

Because, under the proposed rule, each Bank would submit its own capital structure plan, the Finance Board cannot quantify precisely the costs and benefits of the rulemaking at this time. Generally, there may be significant initial costs associated with the development of each Bank's capital structure plan and with each Bank's conversion to its new capital structure. However, the agency anticipates that the new capital regulations, in combination with other recently-adopted regulations that will become fully effective once the new capital structure is in place, ultimately will benefit both the Banks and their members by giving the Banks greater operational flexibility. This will enable the Banks to help their members to compete more effectively in the housing finance and community lending marketplace, which, in turn, will assure that the GSE benefit will accrue more efficiently and effectively to consumers.

Risks:

As the safety and soundness regulator of the Banks, the Finance Board is responsible for ensuring that the Banks are managing their risks adequately. As mentioned above, under the proposed capital rule, each Bank would be required at all times to hold risk-based capital in an amount commensurate with the level of credit risk, market risk and operations risk to which the Bank is exposed through its business activities. Consistent with the Modernization Act, the Finance Board has recently enacted a number of regulations under which the Banks will be permitted to undertake a broader range of business activities and to make a broader range of investments than they have in the past. These new authorities will become fully effective for each Bank as that Bank's new capital structure is put into place.

The risk-based capital requirements, as proposed, are intended to permit the Banks to incur the risks associated with these new activities so long as these risks are adequately capitalized. This is consistent with the manner in which depository institutions and the other housing GSEs are required to manage their risk and contrasts with the old regime under which risk was managed through detailed restrictions on business and investment activity imposed upon the Banks by the Finance Board. The agency believes that, under the new regime, the Banks would be able to expand their business operations to more fully serve their member institutions and, ultimately, the American consumer, while at the same time adequately managing the risks that may arise from these business activities.

Timetable:

Action	Date	FR Cite
NPRM	07/13/00	65 FR 43408
NPRM Comment Period End	11/20/00	
Final Action	01/00/01	
Final Action Effective	03/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

Thomas E. Joseph
Attorney-Advisor
Federal Housing Finance Board
1777 F Street NW.
Washington, DC 20006
Phone: 202 408-2512
Fax: 202 408-2580
Email: josepht@fhfb.gov

RIN: 3069–AB01

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FEDERAL MARITIME COMMISSION (FMC)

Statement of Regulatory and Deregulatory Priorities

The Federal Maritime Commission's (Commission) regulatory objectives are guided by the Agency's basic mission. The Commission's mission is to administer the shipping statutes as effectively as possible to provide an efficient, economic, and nondiscriminatory ocean transportation system in an environment free of unfair foreign maritime trade practices. The Commission's regulations are designed to implement each of the various statutes the Agency administers in a manner consistent with this mission and in a way that minimizes regulatory costs, fosters economic efficiencies, relies on the marketplace to determine industry growth, and promotes international harmony.

Recent legislation altered significantly the Federal regulatory scheme regarding international ocean shipping. The legislation required new regulations, as well as the revision of many of the Commission's substantive regulations. One of the principal changes was the elimination of the requirement that carriers file tariffs with the Commission listing their rates and charges. Carriers are now required to publish their rates in private automated systems. The Commission continues to assess its regulations implementing this requirement, as well as other requirements of the new legislation.

The recent rulemaking process uncovered concern by common carriers as to the content requirements of agreements filed with the Commission. Carriers have expressed a desire for better delineation as to what matters do or do not have to be filed and have suggested that the Commission's rules should provide protections for confidential business information, provide maximum flexibility for carriers to modify cooperative arrangements, and include guidance tailored for different types of agreements. Therefore, the Commission initiated an inquiry to solicit comments from the ocean transportation industry and the general public to assist the Commission in formulating new rules governing content requirements. This matter will be considered during calendar year 2000.

The principal objective or priority of the Agency's current regulatory plan will be to continue to assess major existing regulations for continuing need, effectiveness, burden on the regulated industry, fairness, and clarity.

The Commission continues to have under review, *inter alia*, regulations regarding passenger vessel operator financial responsibility and co-loading arrangements between non-vessel-operating common carriers. The Commission's review of existing regulations exemplifies its objective to regulate fairly and effectively while imposing a minimum burden on the regulated entities, following the principles stated by the President in Executive Order 12866.

Description of the Most Significant Regulatory Actions

The Commission currently has no actions under consideration that constitute ''significant regulatory actions'' under the definition in Executive Order 12866.

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FEDERAL TRADE COMMISSION (FTC)

Statement of Regulatory Priorities

Background

The Federal Trade Commission (FTC or Commission) is an independent agency charged with protecting American consumers from ''unfair methods of competition'' and ''unfair or deceptive acts or practices'' in the marketplace. The Commission strives to ensure that consumers benefit from a vigorously competitive marketplace. The Commission's work is rooted in a belief that free markets work — that competition among producers and information in the hands of consumers brings the best products at the lowest prices for consumers, spurs efficiency and innovation, and strengthens the economy.

The Commission pursues its goal of promoting competition in the marketplace through two different, but complementary, approaches. First, for competition to thrive, curbing deception and fraud is critical. Through its consumer protection activities, the Commission seeks to ensure that consumers receive accurate, not false or misleading, information in the marketplace. At the same time, for consumers to have a choice of products and services at competitive prices and quality, the marketplace must be free from anticompetitive business practices. Thus, the second part of the Commission's basic mission — antitrust enforcement — is to prohibit anticompetitive mergers or other anticompetitive business practices without unduly interfering with the legitimate activities of businesses. These two complementary missions make the Commission unique insofar as it is the Nation's only Federal agency to be given this combination of statutory authority to protect consumers.

The Commission is, first and foremost, a law enforcement agency. It pursues its mandate primarily through case-by-case enforcement of the Federal Trade Commission Act and other statutes. The Commission, however, is also charged with the responsibility of issuing and enforcing regulations under a number of statutes. Pursuant to the FTC Act, for example, the Commission currently has in place 13 trade regulation rules. The Commission also has adopted a number of voluntary industry guides. Most of the regulations and guides pertain to consumer protection matters, and are generally intended to ensure that consumers receive the information necessary to evaluate competing products and make informed purchasing decisions.

Gramm-Leach-Bliley Initiative

The Gramm-Leach-Bliley Act, Pub. L. No. 106-102, was enacted on November 12, 1999.[1] Title V (Privacy) Subtitle A (Disclosure of Nonpublic Personal Information), sections 501(b) and 505(b), require the Federal Trade Commission and the Securities and Exchange Commission to implement and enforce appropriate standards for financial institutions to safeguard customers' records and information (safeguards standards) by rule. The Commission has published a request for comments and, after the comments are reviewed, plans to publish a Notice of Proposed Rulemaking to further implement the statutorily mandated safeguards standards.

Ten-Year Review Program

In 1992, the Commission implemented a program to review its rules and guides regularly. The Commission's review program is patterned after provisions in the Regulatory Flexibility Act, 5 USC 601 *et seq.* Under the Commission's program, however, rules are continually reviewed at least every ten years, not just once as usually required by section 610 of the Regulatory Flexibility Act. This program is also broader than the review contemplated under the Regulatory Flexibility Act, in that it provides the Commission with an ongoing systematic approach for seeking information about the costs and benefits of its rules and guides and whether there are changes that could minimize any adverse economic effects, not just a ''significant economic impact upon a substantial number of small entities.'' The program's goal is to ensure that all of the Commission's rules and guides remain beneficial and in the public interest.

As part of the 10-year plan, the Commission examines the effect of rules and guides on small businesses and on the marketplace in general. These reviews often lead to the revision or rescission of rules and guides to ensure that the Commission's consumer protection and competition goals are achieved efficiently and at the least cost to business. In a number of instances, the Commission has determined that existing rules and guides were no longer necessary or in the public interest. As a result of the review program, the Commission has repealed 48 percent of its trade regulation rules and 52.5 percent of its guides since 1992.

Calendar Year 2000 Reviews

As part of the Commission's 10-year review program, in 2000 the Commission initiated reviews of one rule and one industry guide. They are: the Telemarketing Sales Rule, 16 CFR part 310, and the Guides for the Household Furniture Industry, 16 CFR part 250. Three additional Guide reviews, previously scheduled to commence in 2000 under the Commission's tentative review schedule, have been deferred.[2] The Commission will commence its review of these Guides at a later date.

All of the matters scheduled for review this year pertain to consumer protection and are intended to ensure that consumers receive the information necessary to evaluate competing products and make informed purchasing decisions. For example, the Telemarketing Sales Rule (TSR), 16 CFR part 310, was adopted pursuant to the Telemarketing and Consumer Fraud and Abuse Prevention Act, 15 USC 6101-6108. The Rule requires telemarketers to disclose certain material information; prohibits misrepresentations; limits the times of day telemarketers may call consumers; prohibits calls to a consumer who has asked not to be called again; and sets payment restrictions for the sale of certain goods and services. The Commission began its review of the Rule by holding a forum on the do-not-call provision, followed by a request for comments and a public forum on July 27-28, 2000. The staff will make its recommendations to the Commission concerning the review by the end of the calendar year. In addition, the Commission will report to the Congress on the results of its evaluation of the Rule's operation.

This year, the Commission also began its review of the Guides for the Household Furniture Industry (Furniture Guides), 16 CFR part 250, which were issued on December 21, 1973. The Commission requested comments about the overall costs and benefits and the continuing need for the Furniture Guides. *See* 65 FR 18933 (Apr. 10, 2000). The Furniture Guides generally advise members of the furniture industry to make affirmative

[1] The Commission previously published its final rule implementing other Gramm-Leach-Bliley requirements in its Rule on Privacy of Consumer Financial Information, 16 CFR Part 313. *See* 65 FR 33646 (May 24, 2000).

[2] In publishing the regulatory review schedule each year, the Commission indicates that the tentative timetable may be modified in the future to incorporate new legislative rules, or to respond to external factors (such as changes in the law) or other considerations. *See, e.g.,* 64 FR 3668 (Jan. 25, 1999).

disclosures of product facts, which, if known by a purchaser, would influence the purchasing decision. The specific disclosures concern identification of the types of wood and outer coverings or stuffings used in furniture. These disclosures are designed to prevent consumers from being misled that the product is different from that which is actually being offered. To that end, the Commission's request for comments included eleven questions concerning the continued utility of the Furniture Guides. The comment period, originally scheduled to close on June 9, 2000, was extended until July 10, 2000, at the request of the American Furniture Manufacturers Association. *See* 65 FR 37317 (Jun. 14, 2000).

Reviews in Process

In 1999, the Commission began its regulatory review of certain aspects of the Funeral Industry Practices Rule (Funeral Rule), 16 CFR part 453. The Funeral Rule, which became effective in 1984, and was amended in 1994, requires providers of funeral goods and services to give consumers itemized lists of funeral goods and services that not only state price and descriptions, but also contain specific disclosures. The rule enables consumers to select and purchase only the goods and services they want, except for those which may be required by law and a basic services fee. Also, funeral providers must seek authorization before performing some services, such as embalming. In addition to an assessment of the rule's overall costs and benefits and continuing need for the rule, the Commission's review will examine whether changes in the funeral industry warrant broadening the scope of the rule to include non-traditional providers of funeral goods or services and revising or clarifying certain prohibitions in the rule. *See* 64 FR 24249 (May 5, 1999). In response to requests of industry members, the Commission determined to extend the comment period. A public workshop conference was held on November 18, 1999, to explore issues raised in the comments submitted. Staff expects to forward its recommendation to the Commission this fall.

The Commission's review of the Franchise Rule, 16 CFR part 436, is also continuing. The Commission accepted comments on a Notice of Proposed Rule Making with the text of a revised rule until December 21, 1999, and rebuttal comments until January 31, 2000. The proposal addresses issues including: (1) changing the timing for making disclosures; (2)clarifying the application of the rule to international franchise sales; (3) expanding the rule to require additional disclosures, including pending franchisor initiated lawsuits involving the franchise relationship, franchisor use of gag clauses and, in some instances, trademark specific franchisee associations; (4) permitting disclosures through electronic media, including the Internet; and (5) expanding the rule's exemptions to address sophisticated investors. Staff expects to forward its report to the Commission next spring.

In addition, the Commission's review of the Pay-Per-Call Rule, 16 CFR part 308, is proceeding. The Commission has held workshops to discuss proposed amendments to its Pay-Per-Call Rule including provisions to combat telephone bill cramming — inserting unauthorized charges on consumers' phone bills — and other abuses in the sale of products and services that are billed to the telephone including voicemail, 900-number services, and other telephone base information and entertainment services. The most recent workshop, held May 20 and 21, 2000, focused on discussions of the use of 800 and other toll-free numbers to offer pay-per-call services, the scope of the Rule, the dispute resolution process, and the need for obtaining authorization from consumers before placing charges on their telephone bills. Staff anticipates forwarding its recommendation to the Commission this winter.

The reviews of the Amplifier Rule, 16 CFR part 432, the Ophthalmic Practice Rule, 16 CFR Part 456, and the R-Value Rule, 16 CFR part 460, are proceeding. Staff has forwarded its recommendation to the Commission regarding the Amplifier Rule and expects to forward a recommendation to the Commission regarding the Ophthalmic Practice Rule in fall 2000.

With respect to Industry Guides, the Commission also has solicited comments on its Guide Concerning Fuel Advertising for New Automobiles (Fuel Economy Guide), 16 CFR part 259, effective in 1975. *See* 64 FR 19720 (Apr. 22, 1999). The Fuel Economy Guide is designed to prevent deceptive fuel economy advertising and to facilitate the use of fuel economy claims in advertising. Since its issuance, the Fuel Economy Guide has advised marketers to disclose the established fuel economy of the vehicle as determined by EPA under the Automobile Information Disclosure Act, 15 U.S.C. 2206, in advertisements that make representations regarding the fuel economy of a new vehicle. These EPA fuel economy numbers also appear on window labels attached to new automobiles. The Commission amended the Fuel Economy Guide in 1978 and 1995 to make it consistent with the Information Disclosure Act changes regarding fuel economy disclosures.

Finally, in response to a petition from industry members, the Commission is reviewing a portion of the Guides for the Jewelry, Precious Metals and Pewter Industry, 16 CFR part 23, to determine whether an amendment is necessary. Although these Guides were reviewed in 1992 under the 10-year plan, the Commission is responding to this petition for revisions to the Guides to address whether there should be additional disclosures to consumers resulting from technological developments in the treatments of diamonds and gemstone jewelry products. *See* 64 FR 30448 (Jun. 8, 2000).

Final Actions

Since publication of the 1999 Regulatory Plan, the Commission has completed several regulatory reviews. The Commission has completed its review of the Care Labeling Rule, 16 CFR part 423, as part of the Reinventing Government effort to revise text in the CFR to reduce burden or duplication and to streamline requirements. On August 2, 2000, the Commission issued its final amended rule, 65 FR 47261. The final rule amendments clarify the reasonable basis standard and update the water temperature definitions to ensure that they conform to current industry standards. The rulemaking record did not support two proposed revisions. The first would have made it mandatory that washing instructions be given in all instances where garments can be washed at home. This change would have mandated a particular instruction rather than leaving it to the manufacturer's discretion. The Commission also concluded that the effect of the proposed amendment was speculative and that changes in the marketplace suggested that regulatory revision may not be needed or appropriate. The second proposed amendment that was not adopted would have allowed a care label for professional wetcleaning. The Commission concluded that amending the rule to allow for professional wetcleaning would be premature because neither a definition nor a test procedure has been developed. The Commission also issued final Appliance Labeling Rules concerning front-loading and top-loading clothes washers, 65 FR 16132 (Mar. 27, 2000), and permitting use of the Energy Star logo on qualifying

energy efficiency labels, 65 FR 17554 (April 3, 2000).

As discussed more fully below, the Commission has determined to rescind two industry guides that were either outdated or unnecessary in light of industry self regulation: (1) Guides for the Law Book Industry, 16 CFR part 256; and (2) Guides for the Dog and Cat Food Industry, 16 CFR part 241. The Commission rescinded the Guides for the Law Book Industry, 16 CFR part 256, because the Guides were overly regulatory and no longer necessary. In rescinding the Guides for the Law Book Industry, the Commission noted that these guides provide overly detailed suggestions regarding presale disclosures, were too narrowly focused, and did not include electronic media and licensing techniques, and thus were outdated. The Commission further noted that rescission of the guides may provide an incentive for associations such as the American Association of Law Libraries (AALL) or Association of American Law Schools (AALS) to adopt their own guides to address their members' most important concerns. Further, if future deceptive practices prove to be a problem in this industry, the Commission can pursue enforcement actions under Section 5 of the FTC Act, 15 U.S.C. 45, as needed on a case-by-case basis. *See* 65 FR 2628 (Jan. 19, 2000).

The Commission also rescinded the Guides for the Dog and Cat Food Industry, 16 CFR part 241. (Dog and Cat Food Guides). The Dog and Cat Food Guides, effective since 1969, advised industry members not to misrepresent dog or cat food in any material respect, including the composition, quality, dietary and nutritional value, or processing methods used in the manufacture or processing of dog or cat food. *See* 64 FR 57372 (Oct. 25, 1999). Industry members were also advised, *inter alia,* against misrepresenting information about the dog or cat food company *(e.g.,* length of time in business, ranking in the industry or ownership of laboratory or other testing facilities) and using deceptive endorsements or testimonials or deceptively claiming that any dog or cat food had received an award. The Commission published a **Federal Register** notice seeking comment on several questions concerning the Guides' provisions. *See* 64 FR 13368 (Mar. 18, 1999). As a result of the comments filed and other information, the Commission determined that the Dog and Cat Food Guides were no longer needed and therefore should be rescinded. Specifically, the Commission stated that guides are particularly useful when they resolve uncertainty over what claims are likely to be considered deceptive. However, the Commission determined that the Dog and Cat Food Guides did not provide such specific guidance except for topics already addressed by pet food model regulations drafted by the Association of American Feed Control Officials (AAFCO) or animal food regulations issued by the Food and Drug Administration. In addition, the Guides do not appear to cover areas where industry members would have difficulty in determining whether specific claims are likely to be deceptive. The Commission also articulated its enforcement policy with respect to this industry and stated that it will evaluate substantiation for dog and cat food claims on a case-by-case basis.

Calendar Year 2001 Reviews

In calendar year 2001, the Commission expects to initiate certain previously scheduled reviews of two rules and two industry guides.[3] Specifically, the agency plans to begin its regulatory review of the Retail Food Store Advertising and Marketing Practices Rule, 16 CFR part 424, and Preservation of Consumers Claims and Defenses Rule, 16 CFR part 433. The Commission also plans to review the Tire Advertising and Labeling Guides, 16 CFR part 228, and the Guides concerning use of Endorsements and Testimonials in Advertising, 16 CFR part 255.

Summary

With regard to both content and process, the FTC's ongoing and proposed regulatory actions are compatible with the President's priorities. The actions under consideration inform and protect consumers and reduce the regulatory burdens on businesses. The Commission will continue working toward these goals. The Commission's 10-year review program is patterned after provisions in the Regulatory Flexibility Act and complies with the Small Business Regulatory Enforcement Fairness Act of 1996. The Commission's 10-year program also is consistent with President Clinton's National Regulatory Reinvention Initiative, which, among other things, urges agencies to eliminate obsolete or unnecessary regulations. The program corresponds as well to section 5(a) of Executive Order 12866, 58 FR 51735 (Sept. 30, 1993), which directs Executive branch agencies to develop a plan to reevaluate periodically all of their significant existing regulations. In addition, the Children's Online Privacy Protection Rule is consistent with the President's Statement of Regulatory Philosophy and Principles, E.O. 12866 section 1(a), which directs agencies to promulgate only such regulations as are, *inter alia,* required by law or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public.

As set forth in Executive Order 12866, the Commission continues to identify and weigh the costs and benefits of proposed actions and possible alternative actions, and to receive the broadest practicable array of comment from affected consumers, businesses, and the public at large. As stated above, since 1992 the Commission has repealed 48 percent of its trade regulation rules and 52.5 percent of its industry guides that existed in 1992 because they had ceased to serve a useful purpose. In sum, the Commission's regulatory actions are aimed at efficiently and fairly promoting the ability of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. Executive Order 12866, sec. 1.

Regulatory Actions

The Commission has no rules that constitute significant regulatory actions under the definition in Executive Order 12866.

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[3] *See* 64 FR 3668-69 (Jan. 25, 1999).

NATIONAL INDIAN GAMING COMMISSION (NIGC)

Statement of Regulatory Priorities

The Indian Gaming Regulatory Act (IGRA or the Act), 25 U.S.C. 2701 et seq., was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (NIGC or the Commission). The stated purpose of the Commission is to regulate the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments. It is the Commission's intention to provide regulation of Indian gaming to adequately shield it from organized crime and other corrupting influences, to ensure that the Indian tribe is the primary beneficiary of the gaming operation, and to assure that gaming is conducted fairly and honestly by both the operator and players.

The NIGC's regulatory priorities for the next fiscal year are to:

1. Develop standards for constructing and maintaining gaming facilities operated on Indian lands.

2. Develop regulations to establish processes for the classification, review, and approval of games and devices used in tribal gaming.

3. Establish a process for the assessment, notification, and collection of debts owed the NIGC resulting from fines assessed by the Chairman for violations of the IGRA.

NIGC

PROPOSED RULE STAGE

171. ENVIRONMENT AND PUBLIC HEALTH AND SAFETY

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

25 USC 2710(b)(2)(E)

CFR Citation:

25 CFR 573

Legal Deadline:

None

Abstract:

It is necessary for the National Indian Gaming Commission to promulgate regulations, which ensure that tribal gaming facilities are constructed and maintained in a manner that protects the environment and the public health and safety.

Statement of Need:

The Indian Gaming Regulatory Act (IGRA) requires that an approved tribal gaming ordinance contain a provision requiring each tribal gaming facility to be constructed and maintained in a manner that adequately protects the environment and the public health and safety (25 U.S.C. 2710(b)(2)(E)). The Commission has determined that standards are needed to ensure compliance with this statutory requirement.

Summary of Legal Basis:

IGRA expressly authorizes the Commission to ''promulgate such regulations and guidelines as it deems appropriate to implement the provisions of the [Act].'' (25 U.S.C. 2706(b)(10)). The Commission relies on this section of the statute to authorize the promulgation of standards for constructing and maintaining gaming facilities operated on Indian lands in a manner that adequately protects the environment and the public health and safety.

Alternatives:

The Commission has no alternative but to promulgate these environmental, health and safety standards for gaming facilities operated on Indian lands.

Anticipated Cost and Benefits:

The potential benefits to this regulatory action are to establish and define for the regulated community the environmental, health, and safety standards it must follow in order to comply with the IGRA, regulations promulgated thereunder, and tribal gaming ordinances. This regulatory action will provide the regulated public with guidance as to the standards the Chairman will use to determine what constitutes an environmental, health, or safety problem sufficient to warrant an enforcement action.

Risks:

There are no known risks to this regulatory action.

Timetable:

Action	Date	FR Cite
ANPRM	04/27/99	64 FR 22588
ANPRM Comment Period End	06/28/99	
NPRM	07/24/00	65 FR 45558
NPRM Comment Period End	11/30/00	
Final Action	08/00/01	

Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

Tribal

Agency Contact:

Christine Nagle
National Indian Gaming Commission
9th Floor
1441 L Street NW.
Washington, DC 20005
Phone: 202 632-7003
Fax: 202 632-7066
Email: christine__nagle@nigc.doi.gov

RIN: 3141–AA17

NIGC

172. • DEBT COLLECTION

Priority:

Other Significant

Unfunded Mandates:

Undetermined

Legal Authority:

25 USC 2713(a)(1)

CFR Citation:

25 CFR 580

Legal Deadline:

None

Abstract:

This regulation will establish a process for the assessment, notification, and collection of debts owed the National Indian Gaming Commission resulting from fines assessed by the Chairman for violations of the Indian Gaming Regulatory Act.

Statement of Need:

The Indian Gaming Regulatory Act (IGRA) provides that the Chairman shall have the authority to levy and collect civil fines against a tribal operator or management contractor of an Indian gaming operation for any violation of IGRA, any regulation prescribed by the Commission, or tribal regulations, ordinances, resolutions approved by the Chairman. The Commission has determined that regulations are necessary for the assessment, notification, and collection of debts owed the NIGC resulting from fines assessed by the Chairman.

Summary of Legal Basis:

IGRA expressly authorizes the Commission to ''promulgate such regulations and guidelines as it deems appropriate to implement the provisions of the [Act].'' (25 U.S.C. 2706(b)(10)). The Commission relies on this section of the statute to authorize the promulgation of standards for collecting civil fines assessed by the Chairman for violations of the IGRA, NIGC regulations, or tribal regulations, ordinances, or resolutions approved by the Chairman.

Alternatives:

The Commission has no alternative but to promulgate this debt collection procedure for gaming facilities operated on Indian lands.

Anticipated Cost and Benefits:

The potential benefits to this regulatory action are to establish and define for the regulated community the procedure by which the Commission will enforce the collection of civil fines assessed by the Chairman. This regulatory action will provide the Commission with a process for the efficient and effective collection of civil fines.

Risks:

There are no known risks to this regulatory action.

Timetable:

Action	Date	FR Cite
NPRM	02/00/01	

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Tribal

Agency Contact:

Lisa L. Atkinson
Office of General Counsel
National Indian Gaming Commission
Suite 9100
1441 L Street NW.
Washington, DC 20005
Phone: 202 632-7003
Fax: 202 632-7066
Email: lisa__atkinson@nigc.doi.gov

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SURFACE TRANSPORTATION BOARD (STB)

Statement of Regulatory Priorities

The Surface Transportation Board (STB or Board) has as its goal, the exercise of regulatory oversight only when necessary to respond to imperfections in the marketplace. Where regulatory oversight is necessary, the STB seeks to ensure that such oversight is exercised efficiently and effectively, integrating market forces, where possible, into the overall regulatory model. In this regard, the STB works to resolve matters brought before it fairly and expeditiously. Through use of its regulatory exemption authority, encouragement of private-sector solutions to disputes, where possible, streamlining of its decisional process, and consistent application of legal and equitable principles, the STB seeks to facilitate commerce by providing an effective forum for dispute resolution and the approval of appropriate business transactions.

The STB continues to develop, through rulemakings and case disposition, new and better ways to analyze unique and complex problems, to reach fully justified decisions more quickly, and to reduce the costs associated with regulatory oversight. In this regard, the STB continues to streamline applicable regulations and the process for handling matters within its jurisdiction.

Set forth as follows is STB's most important regulatory action proposed in FY 2001, Major Rail Consolidation Procedures, STB Ex Parte No. 582 (Sub-No.1). The Board seeks public comment on, and detailed proposals for, modifications to its regulations governing proposals for major rail consolidations.

STB

PROPOSED RULE STAGE

173. ● MAJOR RAIL CONSOLIDATION PROCEDURES, STB EX PARTE NO. 582 (SUB-NO. 1)

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

49 USC 721; 49 USC 11323; 49 USC 11324; 49 USC 11325

CFR Citation:

49 CFR 1180

Legal Deadline:

None

Abstract:

The Surface Transportation Board seeks public comment on, and detailed proposals for, modifications to its regulations governing proposals for major rail consolidations.

Statement of Need:

The action proposed (adoption of new rules to govern the STB's processing and consideration of major railroad merger proposals) is needed because the pertinent existing rules are not adequate to permit the Board to make appropriate public interest determinations regarding major mergers in a railroad industry that is now more concentrated than when the existing rules were adopted. New guidelines and procedures are necessary so that the record in any major railroad merger proceeding filed in the future will have sufficient information to permit interested persons to participate in the process by stating and supporting their positions and to permit the Board to assess the ramifications of the merger proposal in the light of both the input of interested parties and the relevant statutory criteria.

Summary of Legal Basis:

The action is not directly required by statute. Under 49 U.S.C. 11324, however, in considering a major rail merger proposal, the Board is to be guided by the public interest and must consider, at a minimum: the effect of the proposal on the adequacy of transportation to the public; the effect of including, or not including, other rail carriers in particular proposed mergers; the financial aspects of the proposal; the interest of rail carrier employees affected by the proposed transaction; and the effect of the proposed transaction on competition. The rail transportation policy of 49 U.S.C. 10101, which guides the Board in its regulatory activities, also directs it, among other things, to promote safety, efficiency, good working conditions, an economically sound and competitive rail transportation system, and a transportation system that meets the needs of the public and the national defense. The action is necessary to establish revised guidelines to permit the Board to carry out its statutory mandate and to permit members of the public, as well as other governmental entities, to meaningfully participate in the process of assessing major railroad merger proposals in a railroad industry that is now more concentrated than it was when the current regulations were fashioned.

Alternatives:

Action is necessary to establish guidelines and procedures that would permit the STB to make requisite public interest determinations in its review of major railroad merger proposals. The principal alternative was to attempt to have future major rail merger proposals processed under the outdated existing rules.

Anticipated Cost and Benefits:

Costs. The action anticipates some increase in initial costs for merger applicants. The costs would not be incurred on a regular and routine basis but would only be incurred by the carrier applicants when they choose to seek Board approval for a major merger proposal. If focused, relevant information is provided early in the process, however, the development of an adequate record with input from all interested parties should proceed most efficiently, with parties less likely to incur unexpected costs later in the record development and review process.

Benefits. The principal benefit should be a more focused record with fewer extraneous materials, with up-front understanding by parties to the proceedings of what evidence and arguments need to be presented and when. The action should enhance the predictability of the merger review process and of the outcome of that process.

Risks:

The action would reduce the risk of protracted record development with extraneous materials. The risks associated with the action relate to the difficulty for the Board and involved parties with the necessary broad view of a proposed transaction and its anticipated effects. The goal of the action, however, is to permit the needed broad input, review, and consideration to occur in as organized, orderly, and efficient manner as possible.

Timetable:

Action	Date	FR Cite
ANPRM	03/31/00	65 FR 18021
ANPRM Comment Period End	06/05/00	
NPRM	10/03/00	65 FR 58974

Action	Date	FR Cite
NPRM Comment Period End	01/11/01	
Final Rule	06/00/01	

Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Agency Contact:

Julia Farr
Chief Counsel, Office of Proceedings
Surface Transportation Board
1925 K Street NW.
Washington, DC 20423-0001
Phone: 202 565-1613
TDD Phone: 800 877-8339
Fax: 202 565-9002
Email: farrj@stb.dot.gov

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